EXHIBIT 1

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE
IN AND FOR NEW CASTLE COUNTY

DEBORAH A. BARBA and
THOMAS D. BARBA, her husband,

Plaintiffs,

v. C.A. No. N11C-08-050 MMJ

BOSTON SCIENTIFIC CORPORATION,
a Delaware Corporation,

Defendant.

BEFORE: HONORABLE MARY M. JOHNSTON, J. AND JURY

APPEARANCES:

PHILIP T. EDWARDS, ESQ.
Murphy & Landon
and
FRED THOMPSON, III, ESQ.
FIDELMA L. FITZPATRICK, ESQ.
BREANNE V. COPE, ESQ.
Motley Rice LLC
for the Plaintiffs

COLLEEN SHIELDS, ESQ.
Eckert, Seamans, Cherin & Mellott, LLC
and
MATTHEW D. KEENAN, ESQ.
Shook, Hardy & Bacon LLP
for the Defendant

TRIAL TRANSCRIPT
May 18, 2015

DOMENIC M. VERECHIA, RPR
SUPERIOR COURT OFFICIAL REPORTERS
500 N. King Street, Suite 2609, 2nd Floor
Wilmington, Delaware 19801-3725
(302) 255-0710

May 18, 2015
Courtroom No. 8C
9:30 a.m.

PRESENT:

As noted.

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THE COURT: I received the two motions in limine and the two responses and I have reviewed them and I have a few questions.

And I guess since this is Boston Scientific's motion. I'll hear from them first.

MR. KEENAN: Thank you, Your Honor I will be brief since the Court has -- and we filed these because we thought it would avoid sidebars and get some clarity before we begin. We now have the luxury of having the case larger than submitted by plaintiffs so we know what evidence the jury has heard and has not and will not hear. As the Court certainly aware, there's been a lot of discussion about the label of DFU, Dr. Galloway talked about it. The law requires proximate cause and the nexus with the prescriber to whom the directions for

use are directed, and Dr. Carlson was not shown the DFU, did not comment on it, did not say that it was inadequate, and did not say it was adequate for that matter, but its plaintiff's burden. They've lost that nexus with the directions for use in this case.

Because the law is clear that unless and until he has read reviewed and prepared to comment on it in a negative way adverse to the defendants, there's no evidence that it's inadequate in this case. There's no nexus to this case.

THE COURT: Even though he was not provided, or he didn't review that particular document, wasn't there testimony that he said if he had had certain information he would have considered it?

MR. KEENAN: You anticipated my next point and I've got to transcript right here with the Court's permission I'll show it to the Court.

THE COURT: Yes.

(Pause.)

MR. KEENAN: On page 28, Your Honor, it begins on 27, is a series of questions about would you have known, or would this had made a difference. And these are questions that do put into evidence certain issues

that are separate and apart from the directions for use. And these are in the case, and we're -- we will deal with these throughout the case, but these are different than the directions for use. He's talking about, in particular, rates of complication, expected complication would you have -- he says would you have used that information to make further inquiry and the safety and efficacy of the Pinnacle. He says yes. Did Dr. Lee ever advise you that there were higher than expected incident rates with Pinnacle products? Not that I remember. He asked about the FDA, PHN, doesn't recall.

He says if you had that information would have incorporated it? Yes. He doesn't ask would it have changed your prescribing decision, would it made a material difference in how approach this case had you had that information, would you have not used the Pinnacle? Those questions weren't asked.

I'm not here to argue whether or not they made a threshold on those questions. The point I went to make Your Honor, if they raised issues on those topics they have not raised an issue of for directions for use and that is a essential part of the plaintiff's case at this point, and in absence of that nexus they should not

allow Dr. Parisian to comment on the directions for use because they can't make the case the directions for use played any role in prescribing decisions of Dr. Carlson.

I want to raise another issue they've raised with regard to this is the training. Their reply belief and now their effort to identify some deposition transcripts of training with Carlson with a doctor would helped train and him and sales represent that helped in training. Training is out. There is multiple admissions on the record that there's no claim Dr. Carlson was improperly trained. So that's not a consideration for the Court.

If what they want to say and prove is that something was said for training that was false that something was said at the training that was misleading, that Dr. Carlson was handed something that said zero complication rates of the Pinnacle, it's safe, and we have clinical trials, then they need to make that showing. They need to make a showing of something, a statement that was false, it was material, that would have impacted his course of conduct had it turned out to be false. We don't have anything from the training.

What we have is what I've shown you. And

there's nothing specific from Boston Scientific relative to training. There's no specific statement that Boston Scientific made to him that they've been able to prove as false and would have changed his conduct.

So I am not -- don't intend to raise broader issues here about what Dr. Carlson would or would not have done with regard to any issues other than directions for use and training. They haven't made that burden. That door is now closed. So Dr. Parisian should not be allowed to offer opinions on training or the DFU because the requisite foundation hasn't been shown.

THE COURT: Now, I want to see if I understand you. So you are not objecting to Dr. Parisian testifying that there should have been a warning about the difficulty or impossibility of removal.

MR. KEENAN: No, I'm objecting to that because that would be in the DFU.

THE COURT: So what is left of her testimony based on your motions?

MR. KEENAN: A lot. She's going to talk about, I don't know exactly, I'm sure she'll talk about the clearance process. She'll educate the jury about

regulatory framework, how it doesn't equate with safety some of those issues. There's still an abundance of things I expect she's going to comment on. She's going to comment on the field assessment that represents those complaints that Mr. Thompson asked Dr. Carlson about. So there's still an abundance of opinions that she has. She has a very, very long report, and if the Court is concerned we're going to be gutting substantial parts of her opinions, I don't think that's the case at all.

The DFU, you know, Your Honor we had a sidebar during Dr. Galloway's testimony which counsel wanted to use the MSDS with him. They can't use those things because they didn't show it with Dr. Carlson. They didn't show him the MSDS, they didn't ask is this something you should have know, those kinds of opinions were not solicited. There's no nexus, no fit for this case now for those issues, for Dr. Parisian be allowed to talk about first of all prejudicial us, it's going to also mislead the jury because they haven't made the burden to show them that they will need to do.

THE COURT: What if she opines that a reasonable physician would have these things and that be that's the appropriate standard?

MR. KEENAN: That's not in her designation. She doesn't -- she's not offered any opinions about Dr. Carlson, physician care and treatment. She only talks about the company, the company, what companies should do, not physicians what physicians should do. Besides that it would be -- that would be -- that couldn't be relevant testimony when they've already heard from Carlson and he didn't offer those opinions.

THE COURT: Can't you testify if it is the case that the FDA, and federal regulations and the standards underlying those regulations require that certain information be placed in the DFU?

MR. KEENAN: Yes. Yes. For example, the mesh surgical guides document is what we have affirmatively put into evidence that that is standard, what should be in the directions for use. So that would certainly be appropriate, yes. But she does not say anywhere in her report that the MSDS should have been in the DFU. That's not an opinion she's ever had.

THE COURT: So you are not -- the purposes of this motion you are not objecting to Dr. Parisian saying that information on removal and rates of occurrence and permanency should have been in the MSDS?

MR. KEENAN: You mean the DFU?

THE COURT: Yes.

MR. KEENAN: No, because all those bear on directions for uses. Those are all directions for use opinions. And Dr. Carlson did not testify that that information was missing, or if he would liked to have known that. In fact, to the contrary Dr. Carlson said he understood and knew that removal of mesh can be difficulty and it's difficult to get all of it. So just the opposite. The directions for use, I submit respectfully is a very clean shot for this Court because of what the evidence is to this point. If Dr. Parisian was testifying before we heard Carlson it would be a different matter. Now that Carlson has testified and this foundation wasn't laid, it's wholly inappropriate for Dr. Parisian to talk about a document that Carlson testified he reviewed, read, relied upon, was misled by.

And that that adversely effected how he cared for Ms. Barba. Those are very -- the instructions the Court will give to the jury we're going to talk about cause, that the negligence of Boston Scientific must cause injury, and the cause component is now missing from this case on the directions for use.

THE COURT: What about the clinical testing motion?

MR. KEENAN: That, respectfully, is a little bit more nuanced, because I don't think it's necessarily white and black. I would just simply go back to what the Court has commented and opined on in previous hearings here, that there has to be a foundation laid for a duty to perform these clinical trials. And we're talking about a device that's rated by federal law. I believe Dr. Parisian needs to point to a rule, a regulation, or a guidance document that would obligate Boston Scientific to conduct clinical trials.

Her own opinion about what she thinks we should do is not, in itself, admissible and I think that's particularly when we're talking about federally regulated device here. If she wants to point to a rule or regulation something that gives her a platform to express that opinion, that's different. Simply, this is what I think they should do is not sufficient basis for her to express that opinion.

THE COURT: All right. I'd like to address that second issue first. I had interpreted Boston Scientific's argument with regard to clinical testing as

being a foundational argument. Is there going to be a foundation laid?

MR. THOMPSON: Yes, Your Honor. Judge, we're going to go through the 510k process as set out, we are going to show the methods by which Boston Scientific tries to show substantial similarity, tries to show the predicate device, tries to show that there are no new, or novel technological instances. There's actually a flow chart in the 510k that shows it, it goes yes, yes, yes, that's what they did.

However, when there is a new or novel use, the chart makes a left turn and goes over and it invokes and requires heightened scrutiny, and that heightened scrutiny can involve, under the statutes and regulations, it's not simply a common law duty, although we assert that it is an obligation of a reasonable medical device manufacturer, but Dr. Parisian is going to talk in terms of a requirement by the examiner to require additional data, which can involve additional testing and clinical trials.

As a matter of fact, here again, we look behind the curtain, we know that's exactly what they did do in this case. That they did require 522 clinical trials in

order to keep these devices on the market. So that's within the federal regulatory scheme, and we think that Dr. Parisian is perfectly within the realm of reliable information to make those statements to the jury. So that's our position.

THE COURT: What about the foundation with regard to the labeling issue that Dr. Carlson was not --

MR. THOMPSON: Judge, I'm going to fight this more than I should, because, in fact, this is a precursor to the directed verdict motion on the issue of failure to warn. So I treat this very seriously. It doesn't break Dr. Parisian's back not to testify on these particular issues, but the record with Dr. Carlson is not quite what Mr. Keenan says. If I read -- and we've actually cited to the Court three occasions in which Dr. Carlson alluded to information which was not known to him, but if he had known it, he would have taken it into consideration, and he would have altered his decision making with regard to application of the Pinnacle and the Advantage mesh.

THE COURT: That is of what at rate of occurrence and the permanency issues? I don't recall him testifying that it would have made any difference

with regard to removal. And this is just my recollection of his testimony was that he knew that complete removal would probably not be possible.

MR. THOMPSON: My memory was that he said he knew about problems, difficulty of removal. However, that is inextricably twined with the rate. If it's a you one in one thousand chance of removal and it's difficult to remove, that's one thing. If the rate is 30 percent, if you remember that was testimony that was out there that was not brought in before the Court, but if the rate is 30 percent, that rate coupled with the difficulty of removal because a true reason not to do the surgery.

What we did, there's a straw horse aspect to Mr. Keenan's aspect. And that is, he's saying that the law requires me to stand up here hand him the DFU and go through item by item by item, and if I happen to miss one item, well, I've waived that item. I don't believe that that's the case. I think that where we have confronted Dr. Carlson with instances of information that would have changed his decision making, changed his advice to Ms. Barba, that that is a broad enough assertion by the doctor that we can continue and we

canning assert our failure to warn.

There are two other instances in this Dr. Carlson testimony. One of which was the elicited by Ms. Shields on cross-examination, she asked if you had known that the Capio device had a high rate of failure, would that have impacted your thought process. He said well, I wouldn't have used a Capio then. Which, of course, that's the key ingredient to a Pinnacle kit.

The third allusion to it is with regard to Advantage and the TVT and the difference in stiffness. That was elicited directly of Dr. Carlson that he did not -- he was, as a matter of fact, he thought the two were identical. He was unaware of the stiffness and he alluded that if that he would have had to take that into consideration. We believe that on three instances Dr. Carlson said if I had had information that was not available to me, I would have considered it. And we think that that's plenty enough to allow the failure to warn claim to go forward.

You know, like I say, my obligation was to put that DFU in front of Carlson and go down line by line at the risk of waiving each bullet point, then we didn't do that. But I don't believe we're required to do that for

our failure to warn. And I think that the warning label needs to be adequate in order to invoke intermediary and I think we're entitled to put in evidence that the warning label is not adequate.

THE COURT: What about the training issue?

MR. THOMPSON: I should have thought of that. He, in his testimony, alludes to sources of information that he would like to have or not have. He alludes, he says I don't recall if Mr. Lee would be the source. I don't recall if the training course would be the source of his information about the safety and efficacy of the product. But he's identifying that he did look to various sources that originated with Boston Scientific. The training is not that the he was properly trained. The training is that at the training course, an integral part of the training is the DFU. An integral part is the submission, you know, if these doctors were telling the truth, the training course is probably the only time that they actually are instructed on the DFU itself.

And that is in this record that he looked to, without distinction, possibly Mr. Lee's information, possibly the information he gained at the training course. Those are sources of information about the risk

and the adequacies of the warning. And we think that all of that is certainly a basis for Dr. Parisian, in the first instance, to address it. And in the second instance, for us to put that to the jury as a failure to warn count. So thank you, Your Honor.

MR. KEENAN: Three brief points, Your Honor. Last week, two weeks ago, we will not claim he was inadequately trained. As a matter of fact, we will stipulate that Dr. Carlson was quail trained. So if he was adequately trained, I'm a little confused how counsel will be able to see that he was told something that was misleading at the training, that somehow impacted Ms. Barba's care.

Second point, the transcript is very clear about what testimony Dr. Carlson did or didn't give. The complication rate is fair game, and we will fight that. It was asked. I don't think he gave an answer that was totally keep it in play, he didn't say it would have changed my behavior. He said I would investigated more and had there been a follow-up question, had he investigated more an found it was an unacceptable risk benefit, would you have then stopped using it? That's the question that's not asked.

But the transcript of Carlson is very clear and I think it gives the Court great guidance about whether or not directions for use has been raised and put in as a foundation for Dr. Parisian's opinions.

THE COURT: If it weren't in the directions for use, how else could Dr. Carlson received the information about complication rates?

MR. KEENAN: Dr. Carlson could have engaged Boston Scientific. He could have affirmatively asked what the field assessment reflected. Simple truth is here, you'll hear it from regulatory complaint information any company has is not something that can be shared with clinicians, it's highly unreliable and very misleading. Because generally companies will only share those when they think it's very favorable.

If the argument is he should have gotten it, or received it in the some other way like John Lee the sales rep should have told him that, we can fight that. That's a different issues entirely different issues than directions for use. Directions for use out of the case. Even, Your Honor, the TVT, the question was asked of Dr. Carlson page 77, Were you aware of Boston Scientific's Advantage Fit mesh was twice as stiff as at

TVT product? No. Question if you would have known that would have advised Ms. Barba of that? Answer: I'm not sure if the stiffness would play a role. I'm not sure if I would have or not.

So TVT, plainly predicate hasn't been laid for the TVT at all. The Pinnacle, he may have raised it on a few issues that I'm not here to argue about now, but the directions for use, unless the testimony is I find it misleading or inadequate, or I'd wish I would have known more, Dr. Parisian should not be wasting our time or confusing the jury by opining on a document that has no place in how the evidence is going in with respect to Dr. Carlson and his care of Ms. Barba.

THE COURT: Go ahead.

MR. THOMPSON: Your Honor, I believe in our brief, not to belabor the point further, as well, but I believe in our brief we address the standard. And I believe that, in fact, the term is a reasonable learned intermediary. So I do believe there is a function and a requirement that a reasonable learned intermediary would be on notice of either the warning, or not and abide by it, or require additional information.

Also, we've cited to the Court cases in which

the DFU is not the only source of expert information to the physician, but it comes from whatever source. And so, Your Honor, we believe that Dr. Parisian certainly can opine on the adequacy of the DFU. But beyond that, like I say, we're foreshadowing the failure to warn argument that will be coming in a day or two. And we simply believe that we have enough information for the jury to consider this issue.

MR. KEENAN: One final thing. If the evidence was Lee walked into Dr. Carlson's office and said we have a great product. There's no complication. We've had clinical trials, it's great and he used it and those were all you will false statements, then we will then -- we would have affirmatively created duty on the misrepresentation that would be an independent basis for a claim against Boston Scientific. But we don't have that. And they have put all of their eggs on the DFU, and you heard Dr. Galloway talk extensively about the DFU and at that point that wasn't objectionable because they still had a chance to call Carlson, but when they didn't use Carlson to draw specific nexus to the DFU, then the DFU became no longer relevant for this case, maybe for another case, but not this case and there's an

abundance -- I mean, an abundance of case law. In fact, Your Honor, had Dr. Carlson testified in advance of this that he reviewed the DFU, in fact, Dr. Carlson testified he didn't review the DFU and we sought summary judgement on that.

They came forth but he had other training material that he may have relied upon and the Court denied summary judgment motion on that basis. Now we know that the DFU is out, and have they raised other fact issues for other things, I'm not here to argue that. I'm simply here to argue that with respect to the DFU, that burden has not been met, and we should not have to listen to Dr. Parisian talk at length about the DFU and how inadequate it is. The jury doesn't have an appreciation because they haven't heard my closing argument, that the DFU was not shown to Dr. Carlson. He didn't review it. He didn't comment on it. So, therefore, there's no connection to this case. Without that, Dr. Parisian should not be allowed to speak to that.

THE COURT: Let me address the motion about clinical trials first.

I am satisfied with the proffer that foundation

is going to be laid for Dr. Parisian to testify on this issue. I will, however, be listening very carefully to whether or not that proper foundation is, indeed, going to be laid. And I want to again emphasize that Dr. Parisian has been permitted to testify as an expert on FDA and federal regulations.

Now, I have some indication from counsel that this witness tends to go far afield. And we need to make sure and corral this witness that instead of expressing generalized opinions that her opinions be based again on her expertise with FDA approval processes and federal regulations. So that is the first thing.

The second thing is with regard to the labeling motion. I am going to limit any training testimony to whether or not that is information that should have been provided to the physician. I'm not going to let Dr. Parisian talk about the type of training, whether training was adequate, I don't know whether she wants to get into that or not. That issue is only peripherally relevant to specific information.

I believe that there has been sufficient testimony by Dr. Carlson, and also as the parties have been placed on notice in the expert report to talk about

rates of occurrence, and whether that information should have been provided to Dr. Carlson. And it goes to his choice of products. It goes to failure rate. It goes to stiffness. That information is a proper subject of Dr. Parisian's testimony.

Now, it gets a little bit nuanced because it is clear that it is a valid argument by plaintiff, and a valid subject of evidence that certain information, including rates of occurrence, and permanency, and removal issues should have been given to the physician. So while I am cognizant of Boston Scientific's argument, I don't know how else the information could have been provided to the physician except through a DFU or the equivalent. And I do think that because of that, I am going to permit Dr. Parisian to say that the DFU should have included this type of information, but I'm also going to allow Boston Scientific to explore whether that information could have been provided in another manner. And, certainly, Boston Scientific can make the argument that it wasn't necessary that this particular information be provided in a DFU, but could have been provided in another manner, or wasn't necessary to be provided. I think it's a question of fact for the jury

as to whether or not this specific information could or should have been provided in the DFU.

Now, it is entirely possible in theory that upon examination and cross-examination the jury will find that this witness is just opining that this is information that should have been in the DFU and doesn't really have a basis for that in FDA regulations or law. That's entirely possible, could go either way. But I think it's a hotly disputed issue of fact as to whether or not this information should have been provided in this document and in this format. I'm going to let Dr. Parisian opine on that without going too far afield.

MR. KEENAN: There's two other quick issues, Your Honor.

THE COURT: All right.

MR. KEENAN: There is a document that counsel identified last night that he intends to use with Dr. Parisian. And it is on an issue that she's not disclosed on her reliance list. It wasn't subject of our deposition that we had with her. And in the most recent updated, truncated disclosure that we got about a month ago it's not identified in it either. And it is this question of sensitization. I objected to this last

night with Mr. Thompson, told him she shouldn't be allowed to talk about it. And I don't think she should be, because it is not an opinion she's ever expressed before.

THE COURT: What is your response?

MR. THOMPSON: Your Honor, I don't intend to elicit an opinion from her. She is going to give a laundry list of problems and deficiencies in the 510k submission by Boston Scientific. One of those laundry list of deficiencies is that they used inaccurate and the wrong ISO10993 tests. That's actually already in evidence, and I think it's been talked about by two different people. That's simply one more of a list of deficiencies. And it would be -- it would make her testimony incomplete to somehow not let her put that on the list.

THE COURT: Incomplete or not, has that ever been on any list provided in a prior opinion?

MR. THOMPSON: No, Your Honor, no.

THE COURT: Then I'm not going to permit that. Is that it?

MR. KEENAN: I believe it is, Your Honor.

MR. ANIELAK: Your Honor, one quick thing.

THE COURT: Yes.

MR. ANIELAK: In terms of invoking the rule providing trial transcripts to our experts, I wanted to make sure we weren't running afoul, we would like to provide trial transcripts to our experts that will be coming to testify.

THE COURT: Assume there's no objection.

MR. THOMPSON: Since we're out of experts, they're going to get an advantage at our expense, but I don't object to it.

THE COURT: Experts can sit in on all the trial they want so there's no problem with providing them with the transcript.

MR. ANIELAK: Thank you, Your Honor.

(Pause.)

THE COURT: We have a problem with one of the jurors.

(Pause.)

THE COURT: We have received information from jury services that juror No. 12 Emma Tomlinson has fallen down the stairs and is not going to be able to continue as a juror. So that means that we will put the next alternate in juror 12's spot which is Daniel

Kelleher, I mean Stacey Davis. That means we have one alternate left, Daniel Kelleher.

Are we ready for the jury or do we need a break?

MR. THOMPSON: Your Honor, we're ready to go.

THE COURT: All right.

(Pause.)

(The jury entered the courtroom at 10:28 a.m.)

THE COURT: Good morning, everyone.

The plaintiffs may present their next witness.

MR. THOMPSON: Your Honor, we'd like to call Dr. Susan Parisian to the stand, please.

SUZANNE PARISIAN,

having been first called by the Plaintiff was sworn on oath, was examined and testified as follows:

MR. THOMPSON: Good morning Dr. Parisian.

THE WITNESS: Good morning Mr. Thompson.

DIRECT EXAMINATION

BY MR. THOMPSON:

Q. Dr. Parisian -- judge, may I approach?

THE COURT: Certainly.

BY MR. THOMPSON:

Q. Dr. Parisian, I'm going to hand you a document

that's entitled curriculum vitae?

A. Yes, sir.

Q. Can you identify that for me please?

A. Yes, sir. It's my curriculum vitae.

Q. And look through it and see if it's up to date?

A. Yes, sir, and it's also my legal history, my legal testimony history is included here and that would probably be not up to date but the CV is.

Q. All right. I'd like to mark that as the next consecutive Plaintiff's Exhibit. Your Honor, I think we have a an ongoing question as to ultimate use of that exhibit but I did want go ahead and put it in at that time?

THE COURT: Let's mark that.

MR. THOMPSON: Why don't you hand it to me. Let me get it marked. 29. All right.

BY MR. THOMPSON:

Q. Now, let me hand you Plaintiff's Exhibit 29?

A. Thank you.

Q. Dr. Parisian just very briefly I want to go over your background and qualifications. What is your education?

A. I'm a physician an MD. That would be part of

my education.

Q. And where did you receive your medical degree from?

A. University of South Florida in Tampa.

Q. And where did you receive your PHD from?

A. I don't have a PHD. I have a bachelor degree and a master's degree from University of Central Florida.

Q. All right. Doctor after receiving your MD degree, were you licensed to practice medicine in any state?

A. Yes, sir.

Q. Where was that?

A. I practiced and licensed in many states. I originally when I got my MD I went and practiced in the State of South Carolina. And I practiced in North Carolina, South Carolina, California, Michigan. I currently have a license in Arizona and Virginia. So I have licenses in many states.

Q. Doctor, I want to look at your career after graduating from medical school and obtaining a medical license, if it's not delicate what year was that?

A. Oh, it was 1978 a long time ago.

BY MR. THOMPSON:

Q. And tell me your career after 1978?

A. My career is going to sound like I've been many places, but my husband also is a physician so we were trying to put two careers together. After I graduated medical school, I did a flexible internship in Greenville, South Carolina, which is basically general doctor taking care of all kinds of patients. Then I went to North Carolina and was a healthcare doctor, a family practitioner, general practitioner type doctor with the health departments. And after that I worked in an emergency room. I was president of a company called mountain emergencies in Durham, North Carolina. Then I went back to do training in pathology. So I'm board certified in anatomic and clinical pathology. So there's been periods of time when I have been doing general practice, and periods of time when I've been doing pathology. Eventually and the reason I'm sitting here today is because I went to work for the FDA.

Q. In your tenure at FDA, did you have opportunity to consider applications or submissions from corporate sponsors of new medications or devices?

A. Yes. That was what I did there I was looking

at both premarket, which would market applications and post market issues that would occur after products were marketed. So I was what they called a medical officer. I was in the center for devices radiological health, CDRH at the FDA that oversees medical devices. So I looked at pre-market applications post-market issues, yes, I did.

Q. Doctor, after leaving the FDA, did you continue in your career as a medical device evaluator or examiner?

A. Well, not after leaving the FDA, but I worked for industry to develop product applications to get cleared by, or approved by the FDA. So for the last 20-years -- I left the FDA in 1995. So for the last 20 years I've been involved with FDA related issues for manufacturers to get new products, and looking at applications.

Q. All right. Certainly here today, you're acting as an expert witness in a products liability trial. That's one of the things you do, as well; is that right?

A. Yes, sir.

Q. Now, Doctor, am I correct in saying that you are in the twilight years of your practice; is that

right?

A. I'm getting pretty gray yeah. Hopefully I'm going to be cutting this down, yes, sir hopefully it's not the twilight of my life.

Q. I didn't mean, if I said that I sure apologize. I didn't mean it?

A. No.

Q. But you are winding down your career?

THE WITNESS: I'm trying to. Yes, sir.

BY MR. THOMPSON:

Q. Doctor, in your experience, and in the things you've done, are you familiar with the organizing statutes and regulations which govern the submission of new product devices to the FDA?

A. Yes, sir. I was required at the FDA to learn about regulations, the food and drug and cosmetic act and what is required for a manufacturer. In fact, I actually had to teach it to other people at the FDA.

Q. Doctor, and does your training and your background give you expertise in reviewing and evaluating submissions by new drug or device applicants?

A. Yes, sir. And particularly as a medical officer, would review them as a physician.

Q. Dr. Parisian, in this case, which is what we're here for on behalf of Ms. Barba, as you know there are two devices that were implanted in Ms. Barba, a device called an Advantage Fit, and a Pinnacle pelvic floor product both manufactured by Boston Scientific. You're aware of that, aren't you?

A. Yes, sir.

Q. And in your review, did you review the various submission documents both for the Advantage Fit and for the Pinnacle?

A. Yes, sir.

Q. And have you -- did you review associated documents and associated information that gives you insight to and allows you to analyze those submissions?

A. Yes, sir.

Q. Doctor, I want to talk just for a minute about the 510k process at the FDA. First question: Does a clearance letter issued by the FDA to a 510k submitter, does a clearance letter mean that the FDA approves of the device?

A. No.

Q. What does it mean?

A. It means it clears the device to begin

marketing. It means that the company has submitted an application to the FDA that has supported, that they are substantially equivalent just like somebody else that's already being marketed for the same intended uses. And so that there has been a product already marketed for that intended use, is used by the FDA then to look at the next product and say well, this is just like that.

There aren't new issues of safety and effectiveness, so you can begin marketing. 510k are submitted when products haven't even been made yet. So the company is saying we're making this product and it's going to be just like the other guy's that's already been marketed for the same use.

Q. Is there any requirement that the product be a better product than anything on the market?

A. It has to be at least equal. It can't worse, it can't be inferior, it can be better. The FDA is not going to prevent something from being better or it cannot be worse or new risks that haven't been addressed by the company.

Q. When the submission is made by an applicant under a 510k, does the FDA test that product?

A. No. It's a paper application. When I first

went to the FDA, I'm going to see devices. So you're looking at paper. It's basically a paper document that the company tells you this is how this is going to perform, this is the type of product it's going to be. So you're looking at only the paper. There's no clinical trials or testing done by the FDA.

Q. All right. Now, with regard to the submission, what information, or what data is relied upon by the FDA in evaluating that submission?

A. It's all the data. In terms of the company has to say that they are being truthful and accurate and giving everything that the FDA needs to put this product on the market. So the FDA is relying on the value of the document and the information that's in it.

Q. Is there any requirement under the regulations that the company disclose material facts known to it with regard to safety and efficacy?

A. Yes. The regulation for 510k, 21 CFR 807 provides manufacturer provide that information, plus the manufacturer has to sign a statement called a truthful and accurate statement saying they're providing all the material facts in this document that the FDA needs to have to make the determination whether a product can

start being marketed.

Q. And does the clearance by the FDA, under a 510k submission process, study all the obligations of a medical device company to provide a safe and effective product to the physicians and the to the public?

A. Can you repeat that?

Q. Does the clearance meant that the FDA that a company has satisfied all its obligations to provide a safe and effective product to physicians and the public?

A. No. All it means is that they have satisfactorily put in an application that allows them to be able to market it. There's a lot of things that the FDA doesn't look at when they look at the application. One would be manufacturing documents, can the company actually make that product? They don't look at the labeling for a 510k, that's the responsibility of the manufacturer, the prescription labeling. So no, it's just a clearance that you as a manufacturer can start marketing the product, but you have to, as a manufacturer, make sure your product that you sell meets a lot of other requirements for manufacturers to sell a product in other states. So it's just a door that allows you to start marketing something. The life of

the product the FDA is not looking at, it's just okay you said you want to market this, okay you can start. You as a manufacturer have all these other duties.

Q. Does anything in a 510k clearance have anything to say about the design, or the installation, or the use the cleared product?

A. Well, it can, if the company provided that information. But the FDA is not looking at those things are well talking about this particular 510k?

Q. Yes, ma'am, I'm talking about the Advantage or the Pinnacle?

A. No, not in terms of the Advantage that was not described in terms of clinical risks for the patient that wasn't described, and the design actually would be under something different than the 510k, it's under 21 CFR 820 under good manufacturing process. So no, it didn't have that information.

Q. Does anything in a 510k clearance relieve Boston Scientific of its obligation to Ms. Barba, for example, to supply a safe and efficacious and nondefective product for her?

A. No, no. It's the 510k clearance is a prohibited act for any manufacturer, 21 USC 331, for a

manufacturer to sell a product in the United States that's not safe and effective. It doesn't matter how it even got on the market, you can't sell a product like that. Whether it's a food, whether it's a drug, whether it's a device.

So the 510k is just to let you market something. But the Act requires that you sell a safe and effective product for patients that are adequately labeled. That's the company's job.

Q. Does a 510k clearance satisfy the obligation of a company to design and make a safe nondefective product?

A. No.

Q. Who exactly is the examiner on a 510k submission for the FDA?

A. The typical 510k examiner and the ones that were involved in these 510ks are usually engineers, chemists, they are not doctors. So therefore the expert in the product is the company, not the FDA.

(Pause.)

MR. THOMPSON: Your Honor, may I approach the witness.

THE COURT: Certainly.

MR. THOMPSON: I'm going to go ahead and mark as Plaintiff's Exhibit 30 a 510k submission for the advantage.

THE WITNESS: Okay.

BY MR. THOMPSON:

Q. I'm also going to put in front of you at the same time Plaintiff's Exhibit 31, which is a 510k for the Pinnacle product?

A. Okay. One has a clip and one doesn't.

Q. Be careful with the one with no clip. We'll get you a clip at the next break.

A. Or rubber band.

Q. Or let's be specific about these two. Do you know who was the reviewer, or who signed off on the clearance letters?

A. The clearance letter for the Advantage was signed off by Mariam Provost, I know Mariam. She's a chemical engineer. The other one was signed off there's been various letters but eventually Mark Melberson who is director of that division and he's also an engineer.

Q. Is either one of them a medical doctor?

A. No.

Q. Dr. Parisian, what is an abbreviated 510k

clearance?

A. An abbreviated 510k was alternative type of 510k submission that was supposed to cut down the review time for the FDA reviewers, to try to streamline the process so the FDA reviewers didn't have to use as much time. It was based on certain changes, in terms of the requirements for manufacturers that manufacturers just provided saying that we met certain guidances, and the review is abbreviated, that's why it's called it an abbreviated 510k.

Q. Is there a time limitation on the FDA for considering a 510k submission?

A. For a traditional 510k is a mandatory 90 days. FDA tries to get through this type of an application in 90 days to decide whether you're going to clear it or not. There's no significant difference for a abbreviated, it's theoretical it's going to take less time, but 90 days is the working time that the reviewer has to get the application done by.

Q. Let's go to page 47 of the Advantage 510k submission. Michael, if you could post that for us so we can have a look at it. We need to blow that up a little bit so we can see it a little bit better. Little

bit more than that. All right.

Doctor, is this -- this is a document that is a flow sheet for the process by which a 510k submission is performed by the examiner; is that right?

A. Correct. A flow sheet would kind of reflect the engineering concept of the FDA, flow sheet. So this is traditional flow sheet that FDA reviewers have to use in order to determine whether to clear something as a 510k, or to ask for additional information, or not to clear it. So this is the process. Every 510k has one of these sheets in the chart. Manufacturers usually provide them, tell the FDA what they think the flow should be. So this is key to the FDA mindset.

Q. All right. Now, Doctor, this is the Advantage 510k submission. And it's dated in 2002; is that right?

A. Yes, sir.

Q. Is there a 510k for the Advantage Fit?

A. No.

Q. Why not?

A. The company made a determination that they didn't need a new 510k for the Advantage Fit.

Q. So from the time that this 510k -- do we know if it was an abbreviated 510k for the Advantage?

A. It originally was yes, sir.

Q. Do we know from 2002, until Ms. Barba in May of 2009 was there any submission with regard to the Advantage or Advantage Fit with regard to clinical information about the Advantage?

A. No.

Q. Now, I've circled, if you noticed I can actually make a mark on this. I've circled the vertical line and I want to go through this just briefly it says the name of this graph is "substantial equivalence." We've already talked about substantial equivalence. That means that -- well, don't worry what I mean. What does it mean?

A. It means that you are the same intended use as some product that's already on the market and you don't raise any new issues of safety and effectiveness that haven't been addressed. So you're substantially equivalent, just like the other guy that's already being marketed. So because you're just like the prior product you can claim all their history of use as support that you should be marketed.

So the opposite in terms of marketing, you're like be everybody else. There's no reason I'm

different. That's what they're trying to say to the FDA in terms of getting clearance. That's the key.

Q. Let's go to the top of this, it says new devices compared to marketed device. That's what you just said?

A. Right. The marketed device would be predicate device the word the FDA would use. So that's the already being sold product.

Q. Do you remember the predicate devices for the Advantage mesh?

A. The Trelex mesh, which was made by Boston Scientific, which is a polypropylene mesh. Biosling. The suspend sling, and the TVT Ethicon TVT tape, which is used for stress urinary incontinence. So those were the predicates that were cited by the company, and they were cited on the cover sheet. So that's what FDA is told. Those are the marketed devices that this new product is like.

Q. Michael, let's go quickly to 34. Keep that one in abeyance and we'll come right back to it. Let's see 34.

A. Okay.

Q. That's what we're looking at?

-01:-04:-53 A. Yes, sir.

-01:-04:-39 MR. KEENAN: Touch the screen.

-01:-04:-35 BY MR. THOMPSON:

-01:-04:-34 Q. These are the predicate device for Advantage as

-01:-04:-32 appears if their submission; is that right?

-01:-04:-31 A. No. These are the predicate devices that's on

-01:-04:-28 this table. When you look at their submission, these

-01:-04:-25 are not all referenced to the FDA, only the ones that I

-01:-04:-21 said, but these are the ones that are on a table. You

-01:-04:-18 have to have a table like this, so they added more

-01:-04:-15 predicates on the table.

-01:-04:-14 Q. All right. So we're looking, there is a Trelex

-01:-04:-10 that we talked about?

-01:-04:-08 A. Right that's Boston Scientific's mesh.

-01:-04:-06 Q. There's something called Insling which is

-01:-04:-01 actually a polyester; is that right?

-01:-03:-58 A. Yes, sir.

-01:-03:-58 Q. Then there's the TVT?

-01:-03:-56 A. Right here.

-01:-03:-54 Q. There's something called a Suspend, which is a

-01:-03:-50 polyether urea urethane elastomer?

-01:-03:-44 A. Right, so it's not polypropylene.

-01:-03:-42 Q. Then there's something called the IVS tunneler?

-01:-03:-37 1 A. Which is polypropylene.
-01:-03:-36 2 Q. And the Biosling bioabsorbable polymer sling
-01:-03:-30 3 which is a bioabsorbable polyester?
-01:-03:-29 4 A. Correct.
-01:-03:-28 5 Q. Then that looks like the Spark and the Uretex?
-01:-03:-24 6 A. Right.
-01:-03:-24 7 Q. So what they've done is they've pulled out
-01:-03:-19 8 other mesh types that are on the market to be look at?
-01:-03:-16 9 A. Right, but they didn't discuss all those in
-01:-03:-12 10 their 510k, they only discussed the TVT and the Biosling
-01:-03:-08 11 and the Suspend and the Trelex. There's other ones
-01:-03:-04 12 here, but they are not all discussed.
-01:-03:-03 13 Q. In fact, there's some problems with these other
-01:-02:-58 14 products, isn't there?
-01:-02:-56 15 A. Yes.
-01:-02:-56 16 Q. There are problems that arose and called the
-01:-02:-51 17 suspension of those sales; right?
-01:-02:-49 18 A. Yes.
-01:-02:-49 19 Q. Let's look at the Trelex mesh. Was that a mesh
-01:-02:-45 20 that was used for pelvic repairs in women's bodies?
-01:-02:-39 21 A. No. And though give what the intended use is
-01:-02:-36 22 over that column. This is what it's cleared for. This
-01:-02:-33 23 is what a manufacturer can market it for, the intended

use. That's what FDA has cleared it to be sold for. So that's the only clearance for Trelex mesh and its basically a general surgical mesh.

Q. For hernias and chest walls?

A. Right.

Q. But it's being cited as a predicate device for an Advantage which is going to be used in the women's pelvis?

A. Well, it's being cited as a predicate for a surgical mesh that's what the FDA is reviewing here. One of the indications would be for the pelvis.

Q. What you're saying is the Advantage was put to the FDA as the substantially equivalent of Trelex?

A. Right.

Q. That's what the examiner saw?

A. Right. It's a surgical mesh. The 510k was called in the application was called a modified Trelex mesh and the cover letter. So the Trelex is a surgical mesh which is already cleared. So that's a predicate.

Q. Let's go down to the TVT, one real quick. Now, that's TVT is actually a brand name; is that right?

A. Right. That's the Ethicon tension free vaginal tape.

-01:-01:-16 Q. And it is also a polypropylene mesh; is that
-01:-01:-12 right?
-01:-01:-12 A. Yes. And they didn't include the clearance for
-01:-01:-09 the TVT here, they have part of it, but they don't have
-01:-01:-04 the essential part of the TVT, which also includes the
-01:-01:-01 clearance of the components that's not listed here. If
-01:00:-58 you looked at the approved indication for use the TVT is
-01:00:-54 not written correctly in terms of the way it's actually
-01:00:-51 cleared.
-01:00:-51 Q. One of the things about the TVT mesh is that it
-01:00:-46 actually has predicate devices that support its
-01:00:-42 clearance, as well?
-01:00:-41 A. Yes, right, it does.
-01:00:-40 Q. And one of the predicate devices for the TVT is
-01:00:-36 what?
-01:00:-36 A. It's Protegen, which is Boston Scientific.
-01:00:-31 Q. What was the recent history of Protegen?
-01:00:-27 A. The company withdrew in 1999 from the market.
-01:00:-24 Q. The reason?
-01:00:-23 A. Because the be variability of performance, it
-01:00:-20 wasn't living up to Boston Scientific's standards for a
-01:00:-18 sling.
-01:00:-18 Q. So what we're seeing with the 510k process is

that you can have a predicate device that's a defective device, but once you get cleared, you're cleared?

A. You're clear.

Q. Is that right?

A. You're cleared.

MR. KEENAN: Your Honor, objection, leading.

THE COURT: Sustained.

BY MR. THOMPSON:

Q. Is there a requirement that a predicate device be looked back to with subsequent devices on 510ks?

A. No. Once you're cleared, you're cleared. You're on the market. There isn't a process for FDA to remove the clearance.

Q. Let's go back to the flow chart.

So we've got the new device as compared to a marketed device?

A. Right.

Q. We compare this to the Marlex and to the TVT, if we're talking about Advantage?

A. Trelex. Trelex and TVT. Yes, sir.

Q. And then the next question; does the new device have the same indication statements?

A. And that's why there's a composite of predicate

devices with different indication statements, because the indication statement that they are requesting is actually more like Biosling's intended use, not TVT.

Q. That's fine. That's my question. In fact, the Advantage indication statement is not quite the same as TVT, is it?

A. No, it's not.

Q. Why does not invoke a no, and push it out?

A. It's because they gave other predicates. Biosling has an intended use similar to what they are requesting.

Q. Biosling is made out of biologic material?

A. Yes, it's a different type of material. Yes, sir.

Q. So let's assume that the answer is yes. So it goes down to what's the next step?

A. The new device may have same intended use and may be substantially equivalent.

Q. And then the next one down?

A. Does the device have the same technological characteristics, design, materials etc. This would also bring in the clinical use, are there new issues in terms of how it's going to be used. That would be in

technology.

Q. The next one down would be what?

A. Are the descriptive characteristics precise enough to insure equivalence, that's for the FDA, has the application been precise enough so the reviewer can make a decision.

Q. Then the answer to that whole column is yes then you get down to approval, or not approval, clearance?

A. Clearance with a 510k right.

Q. Okay. Now, let's go back up. Let's talk a little bit about the Advantage. We talked about the ProteGen that the predicate for the TVT was a polyester product called ProteGen, correct?

A. It was a colligens injected polyester.

Q. And the device for which the TVT is used to the device that is approved to install a TVT is what?

A. Pardon?

Q. Is there an insertion device?

A. When the TVT application 510k came to the FDA, they actually had a clinical study to look at the devices that are used, the accessories to make sure you can actually install the tape into the woman's pelvis.

00:-56:-09 So the TVT, when you look at the clearance, it's not
00:-56:-06 listed correctly on that one sheet. But it includes not
00:-56:-01 as much the emphasis on the tape because the tape it was
00:-55:-57 Prolene which was a mesh and had been used for years it
00:-55:-54 was putting into the woman's pelvis the equipment, the
00:-55:-51 accessories. So the TVT was different. It wasn't the
00:-55:-46 focus of the TVT wasn't the mesh.
00:-55:-44 Q. Let's look at the Advantage, was there an
00:-55:-41 inserter device for the Advantage?
00:-55:-37 A. There wasn't a kit. They basically told the
00:-55:-32 FDA that the physician could use available tools. They
00:-55:-27 didn't describe delivery system. There were things
00:-55:-22 there may be delivery tools, there may not, they don't
00:-55:-17 need to be reviewed they are Class I, they are exempt.
00:-55:-14 Q. If, in fact, there was an intention to use the
00:-55:-11 Advantage as part of the kit and to include an inserter
00:-55:-07 device, is it your opinion that that should have been
00:-55:-04 included in the 510k submission?
00:-55:00 A. Right. That should have been stated in the
00:-54:-58 very first cover letter to the FDA. Instead of saying
00:-54:-53 it was a surgical mesh, they should said it was a kit.
00:-54:-50 There should have been discussion, there should have
00:-54:-48 been photographs of the components what was going to be

used. There are no photographs. It's really getting cleared as a surgical mesh, and the predicates they're citing in the clearance is that it's a surgical mesh.

Q. Now, Dr. Parisian, we've actually heard testimony in this courtroom earlier about the differences between the Prolene mesh of the TVT and the Advantage mesh. Are you familiar the statement or description of the Boston Scientific mesh as being de-tanged?

A. Yes, sir.

Q. What is that?

A. That means that there was, according to the 510k, it was FDA was told it was thermal treatment right at the urethra for their mesh.

Q. And was there any description or disclosure to the FDA that the de- tanged Boston Scientific mesh was twice as stiff, or twice as stiff as the TVT Prolene mesh?

A. No discussion. Because that would have been significant. That would be the change in technological characteristics.

Q. You've anticipated my next question. On this flow chart, if the delivery system that had been

00:-53:-29 disclosed as part of the kit, and if the stiffness had
00:-53:-25 been disclosed in its submission to the examiner, who is
00:-53:-21 the chemical engineer, would this have entailed
00:-53:-16 additional scrutiny by the FDA?
00:-53:-13 MR. KEENAN: Objection may we approach Your
00:-53:-11 Honor.
00:-53:-11 THE COURT: Yes.
00:-51:-04 (The following sidebar conference was held.)
00:-51:-04 MR. KEENAN: Well, we're starting to see
00:-51:-04 Dr. Parisian work her magic. She's going to speculate
00:-51:-04 about what the FDA would or wouldn't have done with
00:-51:-04 information and she's going to continue to opine that
00:-51:-04 the FDA will have taken a certain course of action and
00:-51:-04 this device rules product misleading the FDA and she
00:-51:-04 never been cleared on the market etc., etc., etc., if
00:-51:-04 Mr. Thompson's question was asking about what the FDA
00:-51:-04 would do, can or would likely have done we're seeing her
00:-51:-04 at her best, which is speculating about not talking
00:-51:-04 about what happened, in fact, happened but talking about
00:-51:-04 what she thinks would possibly happen had certain facts
00:-51:-04 been disclosed in a different way.
00:-51:-04 MR. THOMPSON: Judge, I think it's clearly
00:-51:-04 within her expertise and it's within the expertise of an

expert to say if there is a matrix that is used to make decision and if, in fact, there were be additional facts adduced would it have triggered a left turn on the matrix and required that activity by the FDA. We're not insulating. That's simply that's what additional information would cause in the examiner.

MR. KEENAN: If she wants to opine about what she would do when she worked, tell FDA how she would interpret it that's different, that's different, but her talking about what the FDA would have done is completely improper.

MR. THOMPSON: I will restate my question.

THE COURT: Very well.

(Sidebar conference concluded.)

BY MR. THOMPSON:

Q. Dr. Parisian, if the additional stiffness and if the delivery system had been disclosed within the body of the 510k submission, if you were the examiner what would you have done?

A. If I was the examiner, I'd ask for information about the potential risk of having something thickened right at the urethral support. So I would have asked for additional information, which is what the FDA can do

00:-50:-27 1 if there's a potential new issue of safety and
00:-50:-24 2 effectiveness, that allows the FDA then to ask for
00:-50:-21 3 additional information. Particularly, we know with the
00:-50:-17 4 TVT, when they were told about the equipment, the tools
00:-50:-13 5 that the FDA was then able to ask for data to support
00:-50:-06 6 that you could actually use it the way you were
00:-50:-05 7 intending to use it. Without that information the FDA
00:-50:-03 8 can't ask that. They're basing what they can do on what
00:-50:00 9 the company is telling them they are going to be
00:-49:-57 10 marketing.
00:-49:-56 11 Q. All right. Doctor, let me turn from the
00:-49:-52 12 Advantage -- and here again, let me sum up just one
00:-49:-49 13 time. We're talking about the Advantage 510k; is that
00:-49:-46 14 correct?
00:-49:-46 15 A. Yes, sir.
00:-49:-45 16 Q. We're not talking about the Advantage Fit sling
00:-49:-41 17 as we sit here, are we?
00:-49:-39 18 A. Right. Now, the FDA didn't have the Advantage
00:-49:-36 19 name all they had was modified Trelex. There wasn't any
00:-49:-31 20 name given to the FDA for what this mesh what is going
00:-49:-28 21 to be sold as. That's okay. It said to be determined
00:-49:-23 22 or the Trelex mesh modified Trelex mesh which is a
00:-49:-17 23 surgical mesh when they are looking at the 510k.

00:-49:-15 Q. Let's turn our attention to the Pinnacle 510k now. And I want to put that flow sheet back up again please, the same one we just had.

00:-48:-56 Now, between 2002 and 2007, was there any change in the way that the examiner was required to look at the 510k submission?

00:-48:-45 A. No. That flow chart that we looked at still applies, still applies today.

00:-48:-40 Q. So now we're back with a new flow sheet. In fact, having done that, let's go to page 444, please. This is going to be a little bit hard to read because it's light print. But can we blow this up so we can get -- there we go.

00:-47:-58 Dr. Parisian, what is this?

00:-47:-55 A. This is a 510k -- let's see I think -- this is for the Pinnacle 510k and I think this is the 510k clearance letter if we can move it up.

00:-47:-38 Q. No, ma'am, this is a submission letter, I'm sorry, I should have just said that?

00:-47:-33 A. Yes, sir. This is the submission letter to the FDA.

00:-47:-31 Q. I want to start out with, does this letter form a substantive part of the submission?

00:-47:-23 A. This is the first thing the reviewer looks at. So it really sets, after having been a reviewer, it sets what you are going to be looking at in terms of the application.

00:-47:-12 Q. Let's look, first of all, to the second paragraph. Read that for me?

00:-47:-08 A. The proposed mesh is manufactured by Proxy Medical and is identical in terms of mesh characteristics to their previously cleared mesh K 051245. Everything at FDA in terms of devices is set by that identifier number, K for 510k. The only difference between their previously cleared mesh and the BSC proposed mesh are --

00:-46:-37 Q. Let's go to the first bullet point?

00:-46:-35 A. The dimensional shape and size of the mesh, the predicate mesh is a rectangular sheet ten cm by 15 cm, that is cut to size by the physician. The physician would use scissors to cut what they want. The proposed mesh is offered in three configuration, anterior, posterior and total.

00:-46:-13 Q. Your Honor, may I approach the witness for a second?

00:-46:-10 THE COURT: Certainly, you may move freely

throughout the courtroom.

BY MR. THOMPSON:

Q. Dr. Parisian, I've actually tried my hand on drawn something, check behind me and tell me if that's a ten by 15-centimeter rectangle?

A. Yes, sir.

Q. All right. It's at least close enough for government work?

A. For government work it is, yes.

Q. Let's put this on here like this.

(Pause.)

BY MR. THOMPSON:

Q. Let's get this Pinnacle device. Doctor, help me out. Put that in there. Spread that out for me?

A. Yes, sir.

Q. Let's show this to the jury. Doctor, is there anywhere in the world you could take a 10 by 15 centimeter rectangle or square Proxy Polyform mesh and cut a Pinnacle device out of it?

A. No.

Q. All right. As a matter of fact, you and I yesterday I showed you if well actually go to the diagram in the back, it would take a 27 by 21-centimeter

square, or rectangle to be able to cut that out of; is that right?

A. Yes, sir.

Q. Here let me -- everybody okay with that?

So would you use the term identical to describe the new use with the old approved use?

A. No.

Q. Would you believe that the Pinnacle intended use is the same as the Polyform intended use?

A. No.

Q. And would you say that the opening, the size of the device is the same?

A. No. And also you've increased the exposure of the woman to more mesh. So that was a new issue of safety and effectiveness.

Q. Doctor, let's look into the body of the 510k submission. Let's put up 465, Michael.

That is actually included in the 510k submission?

A. Yes, sir.

Q. Now, is there any comment by the examiner on this MSDS, within the Pinnacle clearance process?

A. Not in the clinical.

Q. The following year in 2008, when the Pinnacle two or the uphold is being submitted to the FDA, the examiner does talk about the MSDS; is that right?

A. Yes, sir.

Q. We'll talk about that in a minute, but with regard to Pinnacle submission, the examiner makes no comment on this; correct?

A. Correct.

Q. And Boston Scientific makes no disclosure that the MSDS for Marlex, in fact, contained a prohibition on impermanent implantation in persons; is that right?

MR. KEENAN: Objection, leading.

THE COURT: Can you rephrase?

BY MR. THOMPSON:

Q. Does Boston Scientific make any reference to any restrictions or prohibitions placed on this product by the component manufacturer?

A. No.

Q. Let's look at the Capio tool. And here again, we're talking about the insertion tool (indicating).

Dr. Parisian, this is the Capio instrument; is that right?

A. Yes, sir.

00:-40:-36 Q. Now, Doctor, this is described by the Boston
00:-40:-31 Scientific as a needle holder; is that right?
00:-40:-29 A. Yes, sir.
00:-40:-29 Q. If I looked to the 510k submission, the very
00:-40:-15 beginning there is a requirement that the submission,
00:-40:-11 the submitting party provide a listing of all 510k
00:-39:-59 submissions that have been put in with regard to any
00:-39:-53 item in the proposed device. Is that right?
00:-39:-48 A. That are relevant to that 510k, yes.
00:-39:-46 Q. Let's look at that real quickly. Let's look at
00:-39:-30 437. Is this the page?
00:-39:-25 A. I believe so. Let me see. It's hard to -- I
00:-39:-17 think it is right above where you can't read it.
00:-39:-05 (Pause.)
00:-38:-58 BY MR. THOMPSON:
00:-38:-57 Q. Doctor, what are the two that they refer to --
00:-38:-52 move it down. What are the two 510ks that Boston
00:-38:-44 Scientific referred the examiner to?
00:-38:-42 A. The Polyform predicate, which was the one that
00:-38:-36 was already cleared by Proxy.
00:-38:-33 Q. That's the identical product?
00:-38:-31 A. Right, that's the KO 51243. So the FDA knows
00:-38:-25 same mesh is being used for this product. Then the next

one they have is the Prolift, that's the Ethicon 510k which is pelvic floor repair mesh.

Q. Is there any 510k disclosure for the Capio tool?

A. No.

Q. Is there any way for this examiner, based on this filing, to know that the Capio has been the subject of multiple 510k filings before this?

A. No.

Q. Are you aware that in, I believe, 2002, Boston Scientific went to the FDA and got the Capio tool reclassified as a Class I device as a needle holder. Are you familiar with that?

A. Well, we know there's a 510k. I'm not sure if it's exactly the Capio device, there's a 510k that's cleared as a needle holder.

Q. In any event, the 510k -- the device that's included in the Pinnacle kit is the subject of an earlier 510k submission; is that right?

A. Three, three earlier ones. Yes, sir.

Q. Was the proposed use for the Capio device open surgery supported by an endoscope?

A. Yes, it was an endoscope accessory.

Q. What is an endoscope?

A. An endoscope would be considered a big long black tube that's got a camera at the end so you can see what's going on where you're working.

Q. Is the approved use for the Capio that it would be used in abdominal or -- well, used in surgery where the device could be visually controlled?

A. Right. There would be some visibility.

Q. Are you aware that the Pinnacle device contemplated that the Capio would be used blindly by the inserting physician?

A. Yes, without a trocar. Yes, sir.

Q. And the inserting physician would be expected to find the appropriate place of attachment using anatomical landmarks; is that correct?

A. Yes, sir.

Q. There's not a little camera on the end of the Capio. We just looked at it?

A. That is correct.

Q. Is this a different use for the Capio tool?

A. Then when it was originally cleared for? Yes, sirs.

Q. Is this the first time in the history of the

world that the Capio is being contemplated to use in a woman's pelvis for insertion of a pelvic floor device?

A. Yes, sir.

Q. Now, is the point of insertion of the Capio device, the point of attachment, is that the sacrospinous ligament?

A. Yes, sir.

Q. Is the attachment of an anterior Pinnacle and, here again, you're going to have to bare with me, anterior means front?

A. Right.

Q. Are you familiar with any other device that uses the sacrospinous ligament to attach any sort of hard-point attachment of a device to the sacrospinous ligament from an anterior approach?

A. Not from an anterior.

Q. Is this, in fact, a new and novel use of the Capio?

A. Yes. And it also becomes new and novel based on their marketing, too, what their claims are what it will do. That wasn't what was cleared in terms of a general surgical instrument.

Q. Were there any animal, or clinical testing

provided to the FDA examiner for this 510k proposal?

A. For the Pinnacle?

Q. Yes, ma'am.

A. No, sir.

Q. Okay. Are there new and unknown risks entailed with the method of insertion of the Pinnacle?

A. Yes.

Q. Is the technique for insertion of the Pinnacle novel and unique?

A. In terms of the risks, yes, sir.

Q. Let's go back to the flow chart.

Dr. Parisian, if you were the examiner and you became aware of the prior classification and the prior use of the Capio, you became aware of the intended use of the Capio, the intended attachment points, would you view that as new or novel issues?

A. Yes. They would raise new issues with safety and effectiveness. So that would then open up FDA to ask for additional information.

Q. Let's guide our way down. If you are the examiner, you get the new device --

A. Remember, I would be clinical. The person who is the examiner is an engineer. And so they're relying

on the company to have provided them the safety issues. So they don't have the luxury of having knowledge of this anatomy and the potential risks. That's why they look to the company to provide that information to them.

Q. Where we would make a left turn would be here (indicating)?

A. Right.

Q. Now, in fact, the Pinnacle submission the examiner did have some questions, didn't he?

A. Yes, he did.

Q. And one of the questions he had involved the indications for use?

A. Right.

Q. Is that right? Can we go to 605.

What is -- describe for me what we're looking at?

A. The FDA sends out what they call a request for additional information. So they're allowed to ask some questions because they can't complete their review. So they're asking Boston Scientific for some information about what they're looking at in terms of marketing application.

Q. Now --

A. What I mean, specifically question three that would be the FDA's question and bottom would be the Boston Scientific's response. And I believe -- I don't know if this was sent, or it's a draft letter.

Q. Well, let's just -- whatever it is it's Boston Scientific's responses. The FDA says that the application suggests proposed and predicate devices have the same indications, but we note that your proposed device has an additional sentence, this includes but is not limited to enterocele, rectocele, and cystocele, and vaginal vault prolapse repair?

A. Yes.

Q. And the FDA asked to provide information about that use, those uses; right?

A. Right. They're saying please provide information that identifies the legally marketed device indicated for and those indications. That means you can't 510k it unless there's a device that has that similar indication. You can ask for additional information, you can consider other ways to get this product approved, but you can't use the 510k if you don't have a predicate.

Q. Now, in fact, the anticipated use of the

Pinnacle was to repair enteroceles, rectoceles, cystoceles, and vaginal vault prolapse repair; isn't that right?

A. In terms of the marketing. Yes, sir.

Q. In terms of Ms. Barba?

A. Yes.

Q. The intended use of the Pinnacle was to repair a cystocele?

A. Correct. And there is no surgical mesh that's approved or cleared for that indication.

Q. Well, when we get down to BSC response is what?

A. They delete the indication. They don't tell the FDA that they are planning to market it for it, but we're going to delete the indication.

Q. Did they, in fact, market it for exactly that?

A. Yes.

Q. Okay. Now, the other devices that they referred to are what?

A. What do you mean "the other devices," the predicates?

Q. Let me ask you a couple more questions.

A. Well, the first submission was the Ethicon prolene soft, the Proxy Polyform.

Q. Let's go to Bates 602, please.

Do you recall, this is, I think, this is continuing the FDA examiner's questions about the Pinnacle; correct?

A. Right.

Q. Read me the question?

A. Recently CDRH has received several hundred complaints including five deaths, related to surgical meshes used in gynecological surgery. These reports included patients experiencing adverse events such as mesh erosion, and extrusion, infection, abscess formation, sepsis, as well as organ and vessel perforations, post-operative bleeding, hematoma and incontinence. Many of these patients required additional surgery to remove a portion of the mesh, adhesions, provide antibiotic therapy, blood transfusions and/or repair injuries related to the initial surgery.

Because you proposed a device with a novel design in which physicians may not directly observe device placement, please provide information that addresses the following concerns.

Q. Keep going.

A. Please provide information that support your hypothesis that the Pinnacle pelvic floor repair kit will be a safe and effective active device that avoids the adverse events cited above. Given the novel design of your product, the blinded manner of its implantation, the significance of the adverse events cited above, and the possibility that animal models may not accurately reflect the mechanical forces and stresses in humans implanted with your device, such safety and effectiveness information may include a clinical evaluation of your device.

If you would like guidance on the design of such a study, or submission of an investigational device exempt application, please contact Colin Pollard chief of the obstetrics and gynecology devices branch at and that's his e-mail.

Q. Let's go down to their response. This is Boston Scientific's response. Okay. What's the first thing they say?

A. As discussed previously, in response to question one, the proposed shapes and sizes of the Pinnacle pelvic floor repair kits are not unique and not of novel design. Currently available rectangular

meshes, such as Polyform are cut to size by the physicians prior to placement, and often the physicians may place more than one mesh per patient. Additionally, there are several preshaped products commercially available for the treatment of pelvic organ prolapse that have similar dimensions, shape and size, as the Pinnacle mesh configurations. The placement of the Pinnacle pelvic floor repair kits uses the same anatomical landmarks as the predicate devices.

Q. Scroll that up a little bit for me to the end. The next paragraph, please?

A. Also, as detailed in the response to question one, all of the predicate devices' meshes are delivered to the anatomy using trocar type device, those would be the things so you can see. The predicate device trocars are placed from outside the body, through an incision in the patient's skin, puncturing through bodily tissue, trans cutaneous. The trocar is advanced blindly in the direction of the desired anatomical landmark that is identified through palpation by the physician's fingers from within the vaginal incision. The physician aims and advances the trocar towards his or her finger to create the needed path for mesh delivery.

00:-23:-58 Q. Now, does the response from Boston Scientific recognize that their design is new and novel?

00:-23:-49 A. No.

00:-23:-49 Q. In fact, what do they say?

00:-23:-47 A. They're saying it's not. They're saying it's not unique and not novel.

00:-23:-42 Q. Do they volunteer to address the safety and efficacy concerns of the examiner?

00:-23:-34 A. No.

00:-23:-34 Q. Are they forthcoming with the examiner?

00:-23:-31 A. No.

00:-23:-30 Q. Now, let's go back to the flow chart. Let's look at 488, please.

00:-23:-07 As a result of the examiner's questions they actually followed an amended question for the Pinnacle; is that right?

00:-22:-59 A. Yes, an amended.

00:-22:-57 Q. They added a bunch the additional predicate devices; is that right?

00:-22:-53 A. Yes, sir.

00:-22:-53 Q. In fact they added every major manufacturer of every major pelvic product; is that right?

00:-22:-46 A. Yes, sir.

00:-22:-46 Q. Is there any indication that you have that
00:-22:-40 Boston Scientific sought to have these devices not
00:-22:-31 treated on their own device, but to have them treated as
00:-22:-26 a member of an entire class of devices?
00:-22:-19 A. Yes, sir.
00:-22:-18 Q. I forgot to ask you a summary question.
00:-22:-05 Doctor, based on the information with regard to the
00:-22:-02 Capio, with regard to the attachment of the anterior to
00:-21:-52 the sacrospinous ligaments, with regard to the size of
00:-21:-50 the coverage of the shape, based on those factors, if
00:-21:-46 you were the examiner, would you have viewed this as a
00:-21:-43 new and novel design that required further inquiry?
00:-21:-39 A. I would have. I would have asked for
00:-21:-37 additional information. The FDA was suggesting that
00:-21:-34 when they recommended getting clinical data.
00:-21:-30 Q. Look at this letter dated November 6, 2007.
00:-21:-23 And that is -- it's to Dr. Charles Durfor; is that
00:-21:-17 right?
00:-21:-17 A. Yes, sir.
00:-21:-17 Q. From who?
00:-21:-16 A. From Boston Scientific.
00:-21:-15 Q. Scroll down. Let's look at the third
00:-21:-06 paragraph; "as discussed," read that had for me?

A. As discussed during our telephone call, we realized that FDA is evolving its direction on labeling requirements for surgical meshes used in pelvic floor repair. We understand and appreciate FDA's desire to ensure that the physician and the patient are provided appropriate and current information. We believe that the intent of several of the recommended changes have been met. FDA was asking for a series of changes to the label.

Q. And let's go to the next paragraph. Read that for me?

A. Since we have not found language similar to these recommendations in the labeling of the predicate devices identified in 510k, not in FDA's guidance document for surgical meshes, we are perplexed by FDA's approach to have these modifications implemented only in this submission. We strongly believe that it would be more appropriate and effective for all parties involved in the manufacture and use of surgical meshes for FDA to request that these labeling changes be embraced by the entire surgical mesh industry, not just pelvic, but all surgical mesh. We believe that having similar products in the marketplace with different FDA mandated labeling

will cause confusion among physicians and patients.

Q. All right. Now, let me understand what we're saying here. The FDA is evolving its position; is that right?

A. Yes, sir.

Q. And we've seen the examiner talk about reports of serious adverse events; is that right?

A. Right, evolution, that would be post marked issues, ODE people looking alternative these applications are premarket. So somehow they become aware of these products being used and the post market part of FDA has brought this to their attention. So it's helping to evolve as what's being described here.

Q. You don't what May 12, 2009, is do you?

A. That's Mrs. Barba's surgery.

Q. You do know that. All right May 12, 2009. As of November of 2007, did Boston Scientific embrace the FDA's concern for safety and efficacy of these pelvic floor products and seek additional information to provide safety to Ms. Barba?

A. No.

Q. In fact, what did they propose?

A. They wanted it to be all surgical meshes had to

have the same types of information.

Q. Now, surgical mesh is different than surgical mesh implanted into the pelvic region by pelvic floor kits?

A. That's correct.

Q. How long does it take to get a class-wide label change?

A. It can take at least a year, closer to two years because you're going to have to get all kind of comments periods. FDA has certain requirements in terms of trying to get class label. If they can negotiate it voluntarily, that's much better than having to go through the process of taking an entire class, going through the type of class or type of product change.

Q. The FDA regulations, the prevailing statutes require a medical device company that becomes aware of a safety issue to communicate that; is that right?

A. Yes.

Q. Do they have to wait on the FDA?

A. No. No, the manufacturer can immediately update their labeling, their sales reps. They're required to update their prescription label. They can

communicate at all times with doctors and through their only sales reps and that's usually what they do.

THE COURT: We need to take a break at some point.

MR. THOMPSON: Your Honor, this is fine. I've probably got 20 more minutes on direct.

THE COURT: Let's take a break.

(The jury left the courtroom at 11:38 a.m.)

THE COURT: Dr. Parisian, you've probably been told you cannot discuss your testimony with anyone when you're on a break.

THE WITNESS: Yes, Your Honor.

(A short recess was taken.)

THE COURT: Bring in the jury.

(Pause.)

(The jury entered the courtroom at 11:54 a.m.)

MR. THOMPSON: May it please the Court?

BY MR. THOMPSON:

Q. Dr. Parisian, let me get back to what we were talking about. The FDA issued a clearance letter to Boston Scientific for the Pinnacle?

A. Yes, sir.

Q. And did that clearance letter approve the

Pinnacle?

A. No.

Q. Did it relieve Boston Scientific of any obligation it had to comply with and conform to all regulations?

A. No, it did not.

Q. Did it relieve Boston Scientific of any obligation to provide a safe and nondefective product to the consuming public?

A. No, it did not.

Q. All of those obligations remain with Boston Scientific; right?

A. Correct.

Q. Now, post clearance, is there a branch of FDA that follows and tracks the public health?

A. Yes.

Q. Now, in fact, we saw with the FDA examiner saying we've had several hundred reports?

A. Yes.

Q. What would be the source of those reports?

A. That would be the post-market branch which would be office of surveillance and biometrics more compliance arm they're the ones that look at that type

of stuff, ODE wouldn't.

Q. All right. My efficient staff has picked it up before I'm aware. Is this a copy of the clearance letter?

A. Yes.

Q. And that's included within the package of the 510k that we've already gotten. So we don't need to mark it separately. But is this a clearance letter?

A. Yes, sir. This allows the company to begin marketing the product.

Q. Within the body of the letter, is there a statement that sums up what we were just talking about with regard to the company's continuing obligations?

A. Yes. That's the third paragraph.

Q. Let's highlight the third paragraph. All right. Read that for me?

A. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirement, that's a food and drug and cosmetic act,

including but not limited to registration and listing which is 21 CFR part 807, labeling means they have to create a label. 21 CFR part 801, good manufacturing practice requirements as set forth in the quality systems QS regulation 21 CFR part 820. That's the product in terms of manufacturing where a manufacturer has to do in terms of marketing a product and selling it and making it, and if applicable, it's not here, it's not an electronic device.

So these are the requirements. In the very first paragraph it says we've shown that you're substantially equivalent, that's what you're cleared for. But you describe something, you filled in an application now you can start marketing. Now is the real life of the product is once it gets cleared the manufacturer now has to make sure the product is safe and effective when it's used in patients.

Q. Let's go to July of 2008. This is after the Pinnacle has been cleared. Is there a device that Boston Scientific has submitted called Pinnacle II?

A. Yes. It's the modified Pinnacle, yes, sir.

Q. And, in fact, were there examiner questions with regard to the modified Pinnacle?

00:03:02 A. Yes.
00:03:02 Q. Would you pull that up for me.
00:03:22 (Pause.)
00:03:22 BY MR. THOMPSON:
00:03:31 Q. Let's highlight what the FDA examiner's
00:03:34 question is.
00:03:44 Dr. Parisian, can you identify this document?
00:03:46 A. This is Boston Scientific's responses for the
00:03:51 FDA's questions for additional information for the 510k
00:03:55 which marketed the Uphold device. I'm not sure if this
00:04:01 is the draft there's draft ones. I'm not sure if this
00:04:05 is actual submitted once.
00:04:06 Q. There's a thing that K 081048?
00:04:12 A. That's 510k model for modified Pinnacle II
00:04:16 which is eventually sold for the Uphold.
00:04:19 MR. THOMPSON: Your Honor, I'm not sure if this
00:04:22 group was previously offered in this action but we would
00:04:27 like to offer it.
00:04:29 MR. KEENAN: No objection.
00:04:33 MR. THOMPSON: Certainly I want to offer into
00:04:36 the evidence the two 510ks that were previously
00:04:40 identified.
00:04:40 MR. KEENAN: No objection.

00:04:41 THE COURT: Very well.

00:04:42 BY MR. THOMPSON:

00:04:49 Q. Dr. Parisian, I'm going to hand you Plaintiff's
00:04:53 Exhibit 32, which is hard copy version of what you're
00:04:55 looking at on the screen, okay?

00:04:57 A. Yes, sir.

00:04:58 Q. What is the examiner asking about?

00:05:02 A. This particular case question is about the
00:05:05 Capio. The Capio's suture capturing device. Saying
00:05:11 that there's a large number of adverse events reported
00:05:14 to the FDA regarding tip breakage of the Capio suture
00:05:19 capturing device. Please include instructions on how to
00:05:23 manage such an adverse event during surgery.

00:05:26 Q. And their response is what?

00:05:29 A. The company says we disagree that the number of
00:05:32 adverse events reported to the FDA regarding tip
00:05:36 breakage of the Capio suture capturing device is large.
00:05:40 Our records indicate that there were only 7 MDRs for the
00:05:46 Capio suture capturing device to be packaged within the
00:05:50 pelvic floor repair kits from January 2006 through
00:05:54 May 2008. Over the this same period of time 53 thousand
00:06:00 five hundred Capio suture capturing devices were sold.
00:06:04 Therefore, the average MDR rate is 0.013 percent.

Q. All right. Dr. Parisian, I'm going to put on the board something entitled the Field Assessment Plan, which has already been put into evidence as Plaintiff's Exhibit 18.

Let's turn to page 3 of 34. This is a field assessment of the Pinnacle Anterior Apical PFR kit, do you see that?

A. Yes, sir.

Q. It assesses the performance of the Pinnacle Anterior Apical PFR critic from December '08 -- well, January '08, through December '08; is that correct?

A. Yes, sir.

Q. And it uses a baseline failure rate of 6500 parts per million; is that right?

A. Yes, sir.

Q. Is that an FDA standard?

A. No.

Q. Is that an industry standard?

A. No.

Q. Is that an ISO standard?

A. No.

Q. Is that a ATSM standard?

A. No.

00:07:36 Q. Who made that standard?
00:07:37 A. Boston Scientific. They set that as their
00:07:41 acceptable limit for a number of reports.
00:07:44 Q. And what is the result of the -- before I ask
00:07:49 you that, do they actually have complaints for mesh
00:07:55 suture and Capio?
00:07:57 A. Yes.
00:07:58 Q. And then if you put those together, what is the
00:08:02 complaint rate for --
00:08:05 A. It's much higher than -- yeah, there you go,
00:08:09 complaint rate. So the Capio even exceeds the 65
00:08:14 hundred. But you can look at the mesh complaints and
00:08:17 suture complaints.
00:08:17 Q. If I turn the page to 434, in fact, the average
00:08:23 for the year is 38,250 parts per million?
00:08:27 A. Correct. So that's not acceptable in terms of
00:08:30 65 hundred.
00:08:30 Q. In fact, that's six times the maximum failure
00:08:35 rate or the maximum complication rate?
00:08:38 A. As set by Boston Scientific. Yes, sir.
00:08:40 Q. All right. So let's go back to their response
00:08:43 to the FDA.
00:09:01 It says, we disagree that the number of adverse

events reported to FDA regarding tip breakage of Capio suture capturing device is large. Our records indicated that there were only 7 MDRs for the Capio suture capturing device to be packaged within the pelvic floor repair kits from January 2006 to May 2008. First of all, what is an MDR.

A. That's a Medical Device Report, it's described in 21 CFR 803, and it's a mandatory report filed by industry, or it can be voluntary reports. It's in the FDA's database. It's what the FDA has received. It's not complaints that Boston Scientific has. It's what the FDA has managed to get in their database.

Q. So would we be justified in assuming that although the FDA did not ask for the number of MDRs, that's what Boston Scientific provided as their response to the FDA; is that right?

A. Yeah, the FDA has the MDRs and FDA is saying that it's a large number for the Capio. And the company is saying no, it's not in terms of the reply, and what the FDA is really asking is what is the company receiving for the Capio device because the FDA doesn't have the company's complaint file.

Q. If the field assessment plan is correct, did

00:10:31 the company have information exclusive to itself that
00:10:35 was not available to the FDA?
00:10:37 A. Yes.
00:10:37 Q. If in fact, the company is under an obligation
00:10:42 of being truthful and forthcoming, looking at these two
00:10:47 documents juxtaposed, were they satisfying that
00:10:50 obligation?
00:10:50 A. No, they weren't providing accurate reports to
00:10:55 the FDA.
00:10:55 Q. Now, in this same inquiry of July 17th, 2008,
00:11:04 did the FDA request information about the manufacturer
00:11:10 safety data sheet?
00:11:11 A. Yes.
00:11:11 Q. Now, this is not the Pinnacle request, is it?
00:11:15 A. No. This is later Uphold.
00:11:18 Q. This is a device that became known commercially
00:11:22 as the Uphold; is that right?
00:11:24 A. Yes.
00:11:24 Q. In that request it looks like the examiner
00:11:28 checked the Uphold more closely than he checked the
00:11:34 Pinnacle?
00:11:34 MR. KEENAN: Objection, Your Honor, can we
00:11:36 approach?

00:11:36 THE COURT: Yes.

00:11:44 MR. THOMPSON: Why don't I withdraw that question, if that's okay.

00:11:46

00:11:47 MR. KEENAN: Subject to the Court's previous instruction, yes.

00:11:50

00:11:51 MR. THOMPSON: All right.

00:11:52 BY MR. THOMPSON:

00:11:53 Q. Dr. Parisian was the MSDS, the Manufacturer Safety Data Sheet included in the Pinnacle 510k?

00:11:56

00:12:00 A. Yes.

00:12:00 Q. Was the Manufacturer Safety Data Sheet included in the Uphold or the modified Pinnacle?

00:12:05

00:12:08 A. Yes, same sheet.

00:12:10 Q. Did the examiner in the Pinnacle make any inquiry about the MSDS?

00:12:13

00:12:16 A. No.

00:12:16 Q. Did the examiner in the Uphold make any inquiry about the MSDS?

00:12:16

00:12:21

00:12:23 A. Yes, it did.

00:12:24 Q. In response to the question from the examiner, did Boston Scientific recite prior experience with the Marlex polypropylene resin?

00:12:28

00:12:35

00:12:41 A. Yes.

00:12:42 Q. And did they recite the study, the rabbit study
00:12:51 that was conducted on the Advantage mesh?
00:12:53 A. Yes.
00:12:55 Q. Is, in fact, the Advantage mesh the same as the
00:13:05 Polyform mesh?
00:13:06 A. The resin is, but there's difference in terms
00:13:09 of the final production of the proxy mesh in terms of
00:13:12 trying to make it softer, there's extra steps put into
00:13:16 it.
00:13:16 Q. Did Boston Scientific conduct any additional
00:13:20 testing on the Polyform mesh in response to the
00:13:22 examiner's question about the MSDS sheet?
00:13:26 A. No.
00:13:26 Q. One final thing about the 510k for the
00:13:48 Pinnacle. Let's go to page 464, please.
00:14:17 How about making that bigger. Appendix 9A MSDS
00:14:34 for Marlex HGX 30001?
00:14:39 A. Yes, sir.
00:14:39 Q. In fact is that a truthful and correct
00:14:41 statement?
00:14:41 A. No.
00:14:42 Q. Why not?
00:14:42 A. Because that's not the Marlex mesh. It was

Marlex HGX 0303-01. It's the same Marlex resin used in the Advantage and the same Marlex resin that was used for biocompatibility testing. So that's not the correct resin.

Q. So this is a paragraph and I believe later on in this document it's referred to as a Marlex HGX 300-01?

A. Yes, it doesn't exist, as far as I can find.

Q. And does this speak to the proof reading and care with which this document was assembled?

A. Yes, it's incorrect. It's a major error and it's continues -- but it's not just on this page, it's continuous for --

MR. KEENAN: Objection, Your Honor. Your Honor that's --

THE COURT: Right.

BY MR. THOMPSON:

Q. Doctor, did the FDA, not the part that's looking at clearance. We've talked about that probably more at length than anybody wants to hear about. I'm talking now about the surveillance part. Did there come a time when the FDA surveillance folks ascertained a public health risk from the surgical mesh that was used

in these pelvic products?

A. Yes.

Q. And did they, in fact, advise the manufacturers that they intended to issue a public health notice?

A. Yes.

Q. And did they receive a response from industry prior to the public health notice?

A. Industry and physicians. It was -- yes.

Q. Dr. Parisian, I want to hand you Plaintiff's Exhibit 33, please?

MR. KEENAN: Mr. Thompson, can we approach briefly.

MR. THOMPSON: Please.

(The following sidebar conference was held.)

MR. KEENAN: This is not an objection, per se. But it is a request for original, actually she used this document because this is not a Boston Scientific document, it's not an industry document. Boston Scientific isn't anywhere on this but I will guarantee you see it's by physicians Pelvic Health Coalition. She's going to jump from this to Boston Scientific. This is Dennis miller, who is a physician who happened to be for Pinnacle. He's not an employee, he is a

consultant for Boston Scientific. Boston Scientific is nowhere to be found on this cease, going to use this and talk about Boston Scientific and I'm going to be objecting like crazy. All I'm doing I'll let you lead but this is not a Boston Scientific document and it's an industry document, it's a physician document that if she speculates anything about this I'm going to be on my feet. Fair enough?

MR. THOMPSON: Sure.

THE COURT: Also while we're here I assume since there's been no objection everyone is comfortable with the fact that this witness knows the relative time period she's talking about?

MR. THOMPSON: Your Honor, we are abiding by your ruling.

THE COURT: I knew that you were. I wanted to make sure the witness new.

MR. THOMPSON: Yes, she's not going to volunteer any after 2009.

THE COURT: Very well.

(Sidebar conference concluded.)

BY MR. THOMPSON:

Q. Doctor, I've been will told by my competent

staff that I've given you a bum copy. Let me substitute Plaintiff's Exhibit 32 from that. This is a document from the Pelvic Health Coalition?

A. Yes, sir.

Q. You've had an opportunity to review that document; is that right?

A. Yes, sir.

Q. One of the executive board members is a Dennis Miller, MD. Do you see that?

A. Yes, sir.

Q. Are you aware that Dennis Miller is the inventor and patent holder for the Pinnacle?

A. Yes, sir.

Q. Are you aware that Dr. Miller is a consultant with Boston Scientific?

A. Yes, sir.

Q. Are you aware that Dr. Miller is in fact Boston Scientific's representative on the Pelvic Health Coalition?

A. Yes, sir.

MR. KEENAN: Objection, speculation.

THE COURT: Is that not accurate? Or it's based on the witness's knowledge.

MR. THOMPSON: Your Honor, she's reviewed documents that -- well, I'm talking too much in front of the jury but --

THE COURT: Try to lay a foundation for her knowledge on that issue.

MR. THOMPSON: Let me withdraw that question and we'll move on.

BY MR. THOMPSON:

Q. Doctor, is this a communication to the FDA?

A. Yes, sir.

Q. And is this a document that seeks to have the FDA not issue a public health notice regarding safety issues of pelvic mesh?

A. Yes.

Q. Now, if I could put up -- let me hand you Plaintiff's Exhibit 34. This is a document entitled FDA Medical Devices FDA, Public Health Notification Serious Complications Associated with Transvaginal Placement of Surgical Mesh and Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence?

A. Yes, sir.

Q. Can we figure out the date of this from the date of the document itself?

00:21:28 A. October 20, 2008.
00:21:29 Q. So if we look at the Pelvic Health Coalition
00:21:35 letter, that's this days before; correct?
00:21:38 A. Yes, sir.
00:21:38 Q. Doctor, this public health notice is advice
00:21:44 that the FDA has received over a thousand complaints of
00:21:49 serious injury; is that right?
00:21:51 A. Yes, sir.
00:21:52 Q. Is the MAUDE reporting system a voluntary
00:22:03 system?
00:22:03 A. Yes, sir. Well, not for industry it's
00:22:07 mandatory, for physicians and anyone else you can
00:22:10 report.
00:22:11 Q. Say for example Ms. Barba had a bad outcome
00:22:14 from a Pinnacle surgery, is Dr. Carlson under a mandate
00:22:18 to report that to the FDA?
00:22:21 A. No. He can. Same with Ms. Barba, she can.
00:22:25 Q. In your body of knowledge and within your
00:22:31 expertise as a regulatory expert, is there, in fact, a
00:22:35 rule of thumb as to the expected number of, or
00:22:40 percentage of serious injuries that actually get
00:22:43 reported?
00:22:43 A. Yes in terms of working with this you the FDA

would think of maybe one to 10 percent max is actually getting reported to the FDA. There's numbers to support that. If there's a delay involved like something that's implanted, you would think that your reporting is even less because people just don't associate with the product with the complaint. So FDA looks at reporting, when I was at the FDA looking at MDRs as just a tip of an iceberg. So they're saying there's a thousand -- which is a large number, the FDA is concerned about a thousand reports it has received in its database.

Q. Let's actually scroll down a little bit and put up the nature of the problem, if you could highlight that. Of course, everybody in the regulatory industry knows about this under reporting; is that right?

A. Yes, Congress has been trying to come up with alternative types reporting mechanisms.

Q. If they are reporting on a thousand complaints there's expectation that the actual number of injuries is greatly higher than that; isn't that right?

A. Yes. By the FDA. Yes, sir.

Q. I'm not sure we need to read this exactly. It's now in evidence. But it does report to over the last three years FDA has received over a thousand

reports from nine surgical mesh manufacturers from complications that were associated with surgical mesh devices used to repair POP and SUI. These mesh devices are usually placed transvaginally utilizing tools for minimally invasive placement; right?

A. Yes, sir.

Q. And that's as of October 20, 2008?

A. Yes.

Q. Now, did the FDA continue to seek information regarding complications, and regarding the public safety issues involving these transvaginal replaced pelvic devices?

A. Yes.

Q. Ms. Barba's device was placed on May 12, 2009; correct?

A. Yes, sir.

Q. Are you aware of any communication from Boston Scientific to treating physicians alerting them of the complications that were being seen and were being reported by the FDA?

A. Not alerting them, no, sir.

Q. You've had an opportunity to look at the directions for use of the Pinnacle and the Advantage; is

that correct?

A. Yes, sir.

Q. Do you have any criticisms of the directions for use?

A. Yes.

Q. And what specifically do you think should be placed in those directions to make them more -- to satisfy your concerns?

A. Well, one of the issues is that when a product comes out it's to have a label that is updated with information that's about that product. And so the information has not been updated to include what the risk is for failure, or complications like revision surgery, difficulties with the product, reoccurrence of symptoms. That information has not been added by Boston Scientific for their product. It's a very generic kind of a label that doesn't specifically say what's occurring. There's nothing really alerting physicians about what is happening with Pinnacle as opposed to just a label.

And the DFU, they call it Directions For Use is one document but usually the sales people are updated to also tell the doctor what is the new information that's

now being added to the label. So it's not just the label, that's the label, but labeling is everything the company communities to a doctor, whether through doctor letters, through its sale reps, through patient brochures, that information is not being updated with what's occurring with Pinnacle.

Q. All right. Doctor, let me go back just one last time to the Pinnacle premarket notification. Let's go to 453.

Doctor, we've talked a little bit about how the FDA relies on the truthfulness and accuracy on the applicant who is submitting the request for premarket clearance; correct?

A. Yes.

Q. In fact, that's actually a page in every 510k; isn't that right?

A. It's required that this page be signed and present, otherwise the 510k won't be accepted. Though it is a requirement for the 510k. And it says as required by, and then it has 21 CFR 8097, so it's required.

Q. So Boston Scientific, through its representatives, certifies to the FDA that the

00:28:17 information contained is truthful and accurate. And I
00:28:22 guess I want to ask you one additional thing, and that
00:28:25 no material information has been withheld; is that
00:28:28 right?
00:28:28 A. Correct.
00:28:28 Q. And is there a continuing obligation in Boston
00:28:33 Scientific to forward information that impacts the
00:28:38 safety of its product to the FDA under that requirement?
00:28:42 A. Yes.
00:28:43 Q. Doctor, in your opinion, did Boston Scientific
00:28:54 satisfy the regulations and satisfy its obligations to
00:29:02 Ms. Barba, and to the women of the consuming public to
00:29:06 provide a safe and nondefective product for permanent
00:29:17 implantation into her body?
00:29:19 A. No, it did the not.
00:29:23 MR. THOMPSON: Your Honor, that's all the
00:29:24 questions I've got. Thank you.
00:29:52 (Pause.)
00:29:55 CROSS EXAMINATION
00:29:55 BY MR. KEENAN:
00:30:06 Q. Dr. Parisian, I have to strike a balance here
00:30:09 to make certainly the jury can see this and you can?
00:30:13 A. Do you want me to move over some?

Q. Sure. If you don't mind. Great. Okay.

Dr. Parisian, what percentages of your time in your consulting business do you spend consulting in litigation?

A. Right now as I'm getting ready to retire, it would be probably 100 percent.

Q. And you have, in every case that you have testified in court, you have testified for plaintiffs; right?

A. That I've gone to court for, yes, sir.

Q. And in every case that you've testified in court, a component of the opinions that you express in every case includes an opinion that the label or the warnings was deficient; true?

A. Not necessarily. There's different issues.

Q. My question is: Is inadequate warnings one of the opinions that you've expressed in each one of your cases that you've testified in trial?

A. And I think I've said that I don't remember every one. I'll give you the majority of the time, but I don't know if every single case was involved in that.

Q. Well, can we agree that it may be it would be a component, but it may not be the main component?

A. I think that's what I just said. Yes, sir.

Q. So we talk about how many times you've testified at trials in 2011. I think you have a list there, it's in your curriculum vitae; right?

A. I think so. I've given you a list of everything that I have.

Q. In 2010, I have that you've testified in 17 trials. You'll give me that?

A. I'll give you that. This is a 20-year career, yes, sir.

Q. In 2011, you testified in 11 trials. Sound about right?

A. I'll accept it.

Q. Okay. In 2012, you testified in 16 trials; right?

A. I believe so.

Q. I'm going off of your documents.

A. Yeah. I trust you.

Q. Okay. Well, I appreciate that.

In 2013, the statistics I had was only part of the year for 2013. So in 2013, in nine months you testified in nine trials probably isn't a fair question but do you know whether there was more than nine trials

00:32:49 in be 2013?

00:32:50 A. Probably not. I'm starting to retire around

00:32:53 here, we're coming down.

00:32:54 Q. In 2014, last year, do you know how many trials

00:32:59 you've testified in?

00:33:00 A. Off the top of my head about four. This year I

00:33:07 think I've done two, two or three.

00:33:08 Q. Including today?

00:33:09 A. Yes. That's why I'm retiring.

00:33:13 Q. Well, 17 trials, eleven trials, 16 trials, nine

00:33:19 trials, four trials, you are slowing down a little bit?

00:33:22 A. Yes, sir and some of them were the same issue

00:33:25 in different trials.

00:33:26 Q. But for every time you testify, again, in a

00:33:29 trial you testified for the plaintiff, and you have an

00:33:31 opinion that includes inadequacy of the warning?

00:33:36 A. Yes, as an FDA expert that would make sense and

00:33:40 those are the cases I chose. Yes, sir.

00:33:42 Q. So when we talk about the warning, just so

00:33:45 we're on the same page, if it's a medical device we're

00:33:49 talking about the directions for use, right?

00:33:53 A. For the DFE. Yes, sir.

00:33:56 Q. In your opinion every case that involves a

00:33:56 medical device, you're coming in part of your opinion is
00:33:59 that this document they should have done more?
00:34:01 A. Not necessarily. Because I also was talking
00:34:04 about labeling. And some of the questions about
00:34:06 labeling are marketing questions, and information that's
00:34:10 given out, off-label use so those would all be included
00:34:15 under labeling.
00:34:16 Q. Okay. I'll take that. But your opinion
00:34:18 includes in part boy, drug company or device company,
00:34:22 you should have done more?
00:34:23 A. In the cases I've chosen, yes, sir. I wouldn't
00:34:26 take the case if I didn't think that.
00:34:29 Q. And how much do you -- how much are you paid
00:34:32 for your trial testimony today?
00:34:34 A. I'm being paid $600 an hour. I have a minimum
00:34:39 10 hours, it's a going rate of what I do. And $400 an
00:34:43 hour for study back in my office.
00:34:46 Q. So today you're making $6,000?
00:34:48 A. Yes, sir.
00:34:49 Q. And that's no matter, that's the minimum,
00:34:52 that's a flat rate, six thousand?
00:34:55 A. It's a flats rate. Nobody has me testify in
00:34:59 court longer than 10 hours.

00:35:01 Q. Each of one of these trials, that's per day, if you go to a second day, that's another $6,000?
00:35:08 A. Yes, sir, and as I said, that's the rate.
00:35:13 Q. You've also given sworn testimony in depositions; right?
00:35:16 A. Yes, sir.
00:35:17 Q. And you've given many depositions over the last five years; correct?
00:35:22 A. Well, I know for 20 years, it's 192 depositions, usually 7 hours in length.
00:35:29 Q. So for 20 years, you've had how many depositions?
00:35:31 A. 192, and some of them are multiple times for the same issue.
00:35:36 Q. And what's your rate for per day for deposition?
00:35:40 A. That would be a $600 an hour to get to a deposition because I'm out of my office.
00:35:45 Q. Is there a minimum you charge for that?
00:35:45 A. I believe six hours.
00:35:52 Q. Okay. And so some of the products that you have given testimony in, those are also listed, at least the lawsuits are listed on your curriculum vitae; right?
00:35:54 00:35:57 00:36:15 00:36:20

00:36:22 A. Yes, sir.
00:36:23 Q. So it includes such things as you've given
00:36:25 expert testimony involving hormone drugs, right?
00:36:28 A. In the FDA issues every, one of these is FDA
00:36:32 issues.
00:36:32 Q. We're all on the same page. You've given
00:36:35 testimony or osteoporosis drugs; right?
00:36:38 A. Yes.
00:36:38 Q. You're given testimony regarding bypass surgery
00:36:42 devices?
00:36:42 A. That was investigational use on that one.
00:36:45 Q. Without regard to the use, a bypass surgery
00:36:49 devices you've gave testimony on?
00:36:52 A. Hernia mesh are you talking about inguinal, or
00:36:56 other types of mesh?
00:36:56 Q. You testified in the Kugel mesh?
00:36:59 A. Rights, that's abdominal hernia. I wanted to
00:37:02 be clear on which one you meant.
00:37:04 Q. You've testified in cases of individuals that
00:37:06 took antidepressant drugs; right?
00:37:07 A. Yes, birth defects. Yes, sir.
00:37:08 Q. You've testified in anti- blood clot drugs;
00:37:12 right?

00:37:12 A. Yes, sir, bleeding issues. Yes, sir.
00:37:14 Q. You've testified in diabetes drugs?
00:37:16 A. Heart disease. Yes, sir. Yes, it's 20 years.
00:37:19 Q. You testified in robotic surgery cases; right?
00:37:22 A. Yes, sir.
00:37:23 Q. You testified in a pacemaker case; right?
00:37:25 A. I don't remember if I testified in it.
00:37:27 Q. That was the case we had?
00:37:29 A. Our case, yes. You're right. Yes, we did do
00:37:32 that.
00:37:33 Q. You testified in a seizure case?
00:37:35 A. A seizure case? Are you talking about.
00:37:38 Q. Antiseizure drug?
00:37:40 A. I know what seizures are. I don't remember if
00:37:43 I testified in any.
00:37:43 Q. We'll put a question mark by that. You've
00:37:48 testified in cases involving dietary supplements; right?
00:37:52 A. Yes, ephedrine cases. Yes, sir.
00:37:55 Q. You testified in a heart monitor case?
00:37:58 A. There are multiple ones for that. Yes, sir.
00:38:00 Q. You've testified in some contraceptive cases?
00:38:02 A. Yeah, but those are the some of the hormone
00:38:05 ones.

Q. You testified in a case involving Zimmer in a hip replacement?

A. Yes, sir. These are all FDA products.

Q. You testified in a case involving alcohol prep pads?

A. I did.

Q. On your list. We're going to break for lunch in a about 30 minutes, you're happy to consult your list. I'm just talking about cases in the last 5 years?

A. Okay.

Q. Pain pump case?

A. Yes, we've done a lot of those.

Q. A contact lens case?

A. I don't remember going to court. Go ahead.

Q. I'm not talking about court, I'm talking sworn deposition testimony?

A. Yes. Okay.

Q. Involved in a contact lens solution case?

A. Yes, sir.

Q. You've been involved in absorbable sutures case?

A. Infections. Yes, sir.

Q. Some physicians like absorbable sutures?

00:38:54 A. I like them. I've used them. This was an
00:38:56 infection case.
00:38:57 Q. That was a case you testified he against the
00:39:00 manufacturer of absorbable sutures?
00:39:02 A. For infection, good manufacturing. Had nothing
00:39:05 to do with the labeling.
00:39:07 Q. You testified in a highly cholesterol involving
00:39:10 Crestor?
00:39:10 A. Yes, sir.
00:39:10 Q. You have testified in a case involving prostate
00:39:15 cancer drugs?
00:39:15 A. No, devices.
00:39:16 Q. It wasn't a case involving Lupron?
00:39:19 A. No. That was for in vitro fertilization. I
00:39:24 was in prostate treatment devices.
00:39:28 Q. You were involved in vaccine cases?
00:39:30 A. Yes, sir, issues involving mercury.
00:39:32 Q. And you were involved in a Tylenol case?
00:39:35 A. I don't believe I was involved in a Tylenol
00:39:37 case.
00:39:37 Q. If it's on your list, it's fair to say you were
00:39:40 involved in it?
00:39:40 A. I don't remember being involved -- it doesn't

matter. No, they are all related to how they got on the market in terms of the FDA.

Q. Counsel asked you questions about what you would do with respect to some aspects of the Boston Scientific materials; right, how you would handle them; right?

A. That's what I qualified that as a physician, I would be different than an engineer.

Q. But you obviously had no involvement whatsoever in the Boston Scientific submissions; right, you had long since left the FDA?

A. I left in '95, that's correct.

Q. You haven't-any contact with these individuals about the Boston Scientific submissions, fair?

A. That's correct, and I would be precluded, I believe.

Q. Okay. I'm going to move on. I do want to cover one more thing. If you look at the states, Doctor, you've testified in again that you are reflected in your curriculum vitae. I've made a map here of all the states you've given testimony in at trials. So if I used your list and identified the states where you've given trial testimony, it would be reflected in this

list, fair?

A. I guess so. I haven't seen this picture for a while, hopefully kept it, but I haven't seen it. Are these testimony or things have been filed.

Q. Trial testimony?

A. Okay. Got it.

Q. We can add and Delaware on this list, as well; right?

A. Yes, sir.

Q. Now, I want to shift gears a little bit and talk about sources of information for doctors, okay?

A. Yes, sir.

Q. So when we talk about physicians like Dr. Carlson, he's evaluating whether or not to use a surgical mesh device, whether it's Polyform, or Pinnacle or Advantage, are you with me?

A. Yes, sir.

Q. Doctor have available to them information about risks an benefits of the devices and drugs that they are considering using for their patients. Fair?

A. Where are you talking about?

Q. I'm talking -- doctors have available to them lots of sources of information about the risks and

benefits of a empirical drugs?

A. Specific information.

Q. Surely?

A. Specific information would come primarily from the manufacturer.

Q. If a doctor, for example, is considering using the Advantage or using the TVT, for example, there's going to be a lot of medical literature for them to review, fair?

A. The word lot, there is going to be some, perhaps maybe for a new product there may be, there may not.

Q. But doctors are going to have available to them to Internet to do pub med searches on literature?

A. They do, you're limited to what what's in public.

Q. In the world of transvaginal mesh so slings to street stress urinary incontinence, and products for pelvic organ prolapse there have been hundreds if not thousands of articles published between the early Fifties, Sixties, up through 2008, on that topic, fair?

A. On that topic. Yes, sir.

Q. And you're going to find clinician also that

are going to be finding certain things negative or unfavorable, and you may also find physicians that are partial to this type of therapy through 2009, fair?

A. Yes.

Q. So if a doctor like Dr. Carlson wanted to access that to see what's been published recently, he would have that as a source of information for evaluating a particular risk and benefits for a medical device. Fair?

A. The computer is a source. I don't know what his familiarity is at the time but it is for a physician in general, yes, it would be one source.

Q. It's a wonderful resource, is it not?

A. Well, it's limited in what's in there, but it is a resource.

Q. And the FDA is another resource to physicians; right?

A. Correct. FDA website about this.

Q. You were talking about the complaint database that companies are obligated to report to the FDA. Do you recall that testimony?

A. Yes, sir. MAUDE.

Q. The MAUDE database is accessible online, is it

knit?

A. Well, if you know how to use it. Yes, sir.

Q. And you use it when up prepare your reports, don't you?

A. Yes, sir, but I got trained how to use it when I was at the FDA.

Q. Doctors have access to the FDA website for updates and bulletins and important information about devices, or conditions that involve patients that they're treating. Fair?

A. Yes, anyone does. Yes, sir.

Q. But that's a source of information. So Dr. Carlson, or any doctor for that are matter is going to have the directions for use that comes in the packaging, right?

A. Yes, sir.

Q. He's also going to have the internet and go to pub med and identify recent articles or recent studies or literature that has been published through 2008. Fair?

A. He can.

Q. And he's going to have availability of the FDA and the FDA's website is certainly a lot more user

friendly than it was ever before; right?

A. Yes.

Q. Okay. He's going to have his residency and fellowships, if he's board certified he may have had a fellowship or a additional training beyond his residency; that would be a source of information, would it not?

A. For any hypothetical physician. Yes, sir.

Q. If the physician goes to training courses and training was typically recommended for physicians that were using transvaginal mesh products; right?

A. Yes, sir.

Q. That's a source of information; right?

A. Yes, sir.

Q. We have the conditions or use, directions for use as one source of information; right?

A. Yes, sir.

Q. If they go to medical conferences like the American Urogynecologic Society meeting, there's going to be continuing medical education seminars there, they can go generally and attend to find out about new therapies and devices, those kinds of things. Fair?

A. Yes.

Q. And you would expect that physicians would stay current on such things as important information that may be available to them about the risks or benefits of devices, or drugs that they may be prescribing to their patients. Fair?

A. You mean the physician and regular day practice would I expect them to do all this?

Q. Would you expect that the physicians will be -- should remain current on what's going on with the conditions that they are treating their patients for?

A. They should. And they also rely on the sales rep.

Q. Okay. So bringing it back to Dr. Carlson, these are all things that are available to him if he wants to avail himself of them. Fair?

A. Those would be tools. Yes, sir.

Q. Okay. All right. Now, we were -- in your discussion with Mr. Thompson, he talked about a number of things. One of the things I want to go to is the surgical mesh guidance document. And the surgical mesh guidance document, if you could pull that up. You're familiar with this document; right?

A. Yes, sir, I am.

00:47:20 Q. This is the guidance document for manufacturers like Boston Scientific that are developing the Pinnacle and the Advantage. Fair?

00:47:30 A. Well, it's not a guidance for developing the product. It's a guidance for submitting the 510k to the FDA. That's what it says, premarket notification application. That would be the 510k.

00:47:42 Q. All right. And between the time in 1999, when this was introduced, and let's just take when the Pinnacle was introduced in 2008, there were a number of manufacturers who received clearance from the FDA following this guidance document; right?

00:48:01 A. Well, all the surgical mesh manufacturers. Yes, sir.

00:48:04 Q. And, in fact, there were more than 50 products that had been cleared by the FDA prior to 2008 when this device -- when this -- when Boston Scientific introduced the Pinnacle. Fair?

00:48:19 A. You mean for pelvic organ prolapse?

00:48:22 Q. And stress urinary incontinence?

00:48:24 A. Yes, sir.

00:48:24 Q. Over 50. So if what you say is true that the FDA is reviewing these submissions, and clearing them,

then the FDA is also monitoring their performance in the field through these medical device reports. Fair?

A. Well, they are different people. This is only for premarket group, and you're talking about a post-market group, which is compliance. It would be expected under 21 CFR 807, that the post-market information would be given to the premarket information people, but it's not. So there are different parts of the FDA.

Q. Fair enough. But nowhere in this document does it require clinical trials; right; we can agree on that?

A. No, if there are new issues of safety and effectiveness, I believe there is a discussion you may need to get clinical data. This is for the standard 510k substantially equivalent surgical mesh, but the guidance is a minimum, and I believe there's a section about new issues.

Q. Well, Boston Scientific followed this is in it's submission of then Pinnacle and Advantage Fit; right?

A. What's they stated to the FDA.

Q. And the FDA did not require Boston Scientific to do any clinics of either the Advantage Fit or the

Pinnacle; right?

A. Based on their use of the surgical mesh guidance. Yes, sir.

Q. And this document also includes a discussion about labeling, does it not?

A. For surgical mesh, yes.

Q. Yes.

A. And this is just general mesh, it's not for urological use.

Q. And the discussion of the labeling --

A. Can I see the document you're looking at? I haven't seen it for a while.

Q. Okay. Let me find my page here.

MR. KEENAN: Permission to approach, Your Honor?

THE COURT: Certainly.

THE WITNESS: Thank you. You need it back.

BY MR. KEENAN:

Q. No, you can keep it.

A. Thank you.

Q. Ms. Roberts, if you can go to page 5?

A. Page 5. Yes, sir.

Q. And this is the specific section that discusses

the labeling; right?

A. Yes, sir.

Q. So it says all labeling information for surgical mesh should be supplied, including individual package labeling, package inserts, and available promotional literature. Did I read that correctly?

A. Yes.

Q. The labeling should specify the intended use of the device, contraindications, warnings, precautions, directions for use if applicable, and product claims. Did I read that correctly?

A. Right, that would be the clinical application information.

Q. So this is what the FDA is telling Boston Scientific is part of their surgical mesh guidance document on labeling, true?

A. This is what FDA is telling industry in general if you're going to submit a 510k, you need to have that section.

Q. Okay. I want to talk a little bit about the Advantage submission because counsel asked you some questions about the Advantage and Advantage Fit?

A. Okay.

Q. You're familiar with the submission of the 510k submission of the Advantage fair to say?

A. Yes, sir.

Q. And you have a copy up there, do you?

A. Yes, sir.

Q. Ms. Roberts, if you could go to the Bates No. 23. If you could pull it up the predicate device.

(Pause.)

BY MR. KEENAN:

Q. And the jury has heard about the TVT just to refresh everyone the TVT was a Ethicon Johnson and Johnson product; right?

A. Yes, sir, and it uses prolene mesh.

Q. And it was the very first product to use polypropylene in a sling-like formation; right?

A. In a tape. Yes, sir.

Q. In a tape. And this was a treatment modality that was really new, for lack of any better word, it was a clinical application that was never really -- using the polypropylene never been tried before. Fair?

A. Well, the polypropylene there was a ProteGen before it, but that wasn't polypropylene.

Q. I'm talking about Johnson and Johnson?

00:53:24 A. Right. And FDA asked about how it was
00:53:27 inserted.
00:53:27 Q. All right. Now, the submission that Boston
00:53:33 Scientific made referencing the TVT, with me here?
00:53:38 A. Yes, sir.
00:53:39 Q. Boston Scientific's submission included
00:53:43 published studies of the TVT as part of its submission
00:53:47 for the Advantage. True?
00:53:50 A. There were five, I think you're talking about
00:53:53 Appendix C with there are five references and I believe
00:53:57 there were two that they talk about TVT.
00:54:07 Q. Let's go to -- you have the 510k submission
00:54:10 there for the Advantage?
00:54:11 A. Right. The articles are in Appendix C.
00:54:14 Q. Why don't you go to Bates 163?
00:54:19 A. Okay. At the end.
00:54:21 Q. Yeah.
00:54:31 A. Yes, sir.
00:54:32 Q. With me?
00:54:33 A. Yes, sir.
00:54:33 Q. So this is 2001 and I think to orient the jury,
00:54:41 the Advantage was in 2002; right?
00:54:45 A. Yes, sir.

00:54:46 Q. So 2002 is the Advantage. And here is a study
00:54:50 in 2001 using with the Johnson and Johnson TVT; right?
00:54:56 A. Yes, sir.
00:54:57 Q. And these clinicians report their clinical
00:55:04 findings using the TVT in their patients; right?
00:55:08 A. Yes, sir.
00:55:08 Q. Ms. Roberts, if you could drop down to go to
00:55:16 materials and methods, if you would.
00:55:18 Materials and methods and results and
00:55:27 conclusions. So follow with me here. These urologists
00:55:34 are reporting their clinical findings of the TVT in
00:55:39 2001, and this is part of the submission Boston
00:55:41 Scientific made to the FDA as part of the Advantage
00:55:43 submission; right?
00:55:43 A. Well, yes. This is in Appendix C where
00:55:47 references are given to the FDA it's not every specific
00:55:52 reference, but it's in the reference section.
00:55:54 Q. But these researchers, using the TVT, which was
00:55:58 other predicate for Advantage; right?
00:56:00 A. It was one of the predicates cited.
00:56:02 Q. One of them. It stays, these researchers
00:56:05 report 146 consecutive patients evaluated, all patients
00:56:09 had clinical evidence of SUI. Patients underwent

preoperative evaluation with video urodynamics, symptom questionnaire, and cystoscopy. Postoperatively the patient were evaluated at 3-month intervals by symptom questionnaire, physical examination and post void residuals.

Go down to the results. Average intraoperative time was 27 minutes for sling procedure. There were no intraoperative complications and one major post-operative complication. There was no permanent retention and no erosions. 92 percent of the patients had either no or rare stress incontinence. Postoperatively 7 percent of patients developed de novo urge incontinence. And their conclusion is: We describe excellent results with this new simple, quick, and inexpensive method to correct SUI by placing a proper mesh under the distal urethra. That was their conclusion; right?

A. For the TVT.

Q. That's right. And there was another study that was given to the FDA and it's on the next study, page 168. If you could go to the results. Go up to purpose. And the date of this Dr. Parisian is 2001, right?

A. Yes, sir.

00:57:47 Q. So this is another 2001 study of the TVT made
00:57:55 by Johnson and Johnson that was one of our predicates
00:57:58 for the Advantage; right?
00:57:58 A. One of several that was cited. Yes, sir.
00:58:00 Q. And this clinical study describes that
00:58:11 mid-urethral synthetic sling procedures, that's what the
00:58:12 TVT is, and that's what the Advantage is right?
00:58:14 A. That wasn't what it was cleared as, it was
00:58:18 cleared that it was going to be a surgical mesh. This
00:58:21 is not the TVT, the TVT has differences -- go ahead ask
00:58:24 your question.
00:58:24 Q. My question is: Is the Advantage a
00:58:28 mid-urethral sling?
00:58:29 A. It eventually was when it was marketed by the
00:58:34 company, not in the 510k.
00:58:36 Q. Okay. Mid-urethral sling. So let's go on to
00:58:41 what these clinicians says. They say mid-urethral sling
00:58:47 procedures for treatment of stress urinary incontinence,
00:58:49 paren, SUI, are gaining accessing attention from
00:58:53 surgeons be specializing in female pelvic reconstructive
00:58:57 techniques seeking successful patient outcomes through
00:59:01 reproducible simplicity. Did I read that correctly?
00:59:06 A. Yes, sir.

00:59:07 Q. Their conclusion from this paper is that the
00:59:09 experience with TVT for the last 5 years is encouraging.
00:59:13 At 3-year follow-up for TVT reported cure rates for SUI
00:59:18 range from 80 to 95 percent. Did I read that correctly?
00:59:21 A. Yes, sir.
00:59:22 Q. Okay. A multitude of worldwide reports on PVT
00:59:28 with shorter follow-up support the findings of the TVT
00:59:34 experience. Did I read that correctly?
00:59:35 A. Yes, sir.
00:59:36 Q. Then, Ms. Roberts, if you go down to
00:59:38 conclusions.
00:59:39 The conclusions of these researchers in 2001
00:59:45 talking about clinical studies of the TVT, which was one
00:59:48 of the predicates for the Advantage, with me so far?
00:59:51 A. Yes, as a predicate.
00:59:54 Q. Their conclusion of the TVT is that the
00:59:56 preliminary reports, and the experience at our
00:59:59 institution suggest that the techniques of mid-urethral
01:00:03 synthetic sling placement of TVT and PVT are
01:00:09 reproducible easy to master and minimally invasive with
01:00:12 respect to tissue handling. Goes on to state:
01:00:14 Although, complications with all antiincontinence
01:00:18 procedures exist, understanding the anatomical

01:00:20 considerations and methodology of these unique
01:00:23 procedures should minimize patient morbidity and avoid
01:00:28 patient mortality, and produce a high rate of durable
01:00:32 success. Did I read that correctly?
01:00:34 A. You read it correctly.
01:00:35 Q. Okay. Now, Your Honor I can either jump into
01:00:43 another topic or take a break?
01:00:45 THE COURT: Let's stop here.
01:00:48 All right. We'll take an hour for lunch.
01:00:52 (The jury left the courtroom at 12:57 p.m.)
01:01:23 THE COURT: Anything we need to take up?
01:01:28 MR. ANIELAK: There are some issues on Dr. Dunn
01:01:33 but we can do it when we come back from lunch.
01:01:41 THE COURT: Very well.
01:01:45 (A short recess was taken.)
02:12:41 THE COURT: Please bring in the jury.
02:12:50 (Pause.)
02:12:57 THE COURT: The issues on Dunn that we're going
02:13:01 to discuss later, I have notes here that I've already
02:13:04 resolved main topic areas. Is it something different
02:13:08 than that.
02:13:09 MR. ANIELAK: Sure. Yes, Your Honor.
02:13:12 THE COURT: Okay.

(Pause.)

(The jury entered the courtroom at 2:10 p.m.)

THE COURT: You may continue.

BY MR. KEENAN:

Q. Dr. Parisian, I want to spend about five, 10 minutes on the 510k submission for the Advantage Fit and then I want to transition to the Pinnacle and I'll conclude.

So just a few other questions, Dr. Parisian, about the 510k submission for the Advantage. Are you with me?

A. Yes, sir.

Q. The FDA did determine that the Advantage was substantially equivalent to a TVT; correct?

A. Well, they -- that would be one of the predicates, also to the Trelex mesh they have a biosling indication.

Q. Right but the FDA did ultimately determine it was substantial equivalent?

A. Well, they cleared it.

Q. Which required them to determine it was substantial equivalent?

A. With the surgical mesh what the company

requested not to the surgical kit.

Q. A couple of other questions I want to ask you about the submission to the FDA 2002 for the Advantage Fit and, Dr. Parisian, if you can go to Bates number 074. Ms. Roberts, will you pull out table 11 V1?

A. This is a Advantage 510k, there is no Advantage Fit 510k.

Q. Did I say Advantage Fit?

A. Yes.

Q. This is a Advantage 510k which is in 2002?

A. This was the modified Trelex that the company marketed the Advantage off of. Yes, sir.

Q. In any event, this is a table that identifies some of the testing that Boston Scientific did to compare its proposed Advantage mesh to the predicate mesh TVT?

A. To the mesh, yes, sir.

Q. It includes test on tanged an un- tanged areas correct?

A. Yes, sir.

Q. There's also testing that was done as part of the submission on stiffness; correct?

A. There is a stiffness area there. Yes, sir.

Q. Ms. Roberts, would you go to -- so we have device stiffness and measure bent length; correct?

A. Yes, sir.

Q. And there's another section, Ms. Roberts, if you could go to Bates 114. 114, Dr. Parisian, is some additional testing that was done with respect to tanged and de- tanged areas. Would you go to those places, please.

A. Yes, sir. Okay.

Q. With me?

A. Yes, sir. This is Appendix A.

Q. And I don't want to get into this into too much detail, but obviously they're identifying various tests that were done on the tanged and de- tanged edges; right?

A. Yes, sir.

Q. And, Ms. Roberts, if you could go to page A9 of this document and, Dr. Parisian, if you can go, as well it identifies some stiffness testing, as well. Stiffness was one of the issues you were discussing earlier; right?

A. It was one of the issues that was mentioned. I haven't discussed it specifically.

Q. It's Bates stamped 120. There we go. Stiffness testing. To test stiffness of proposed mesh and compare the values of the predicate mesh TVT, right?

A. Yes, sir.

Q. The conclusion on the next page is as follows: The measured bent length, bending length and fluctuate rigidity of the proposed mesh and predicate mesh are substantially equivalent. That's what's we concluded from the testing?

A. Yes, sir.

Q. Very good. You spoke about something called a field assessment. Do you recall that with counsel?

A. I was asked about it. Yes, sir.

Q. Okay. And a field assessment, there's a field assessment for the Advantage Fit; right?

A. Yes, sir.

Q. You discussed it in your report. We talked about it at your deposition; do you remember?

A. Yes, sir.

Q. I'll hand you Defense Exhibit 43. And permission to approach Your Honor?

THE COURT: Certainly.

BY MR. KEENAN:

Q. Now, a field assessment is an effort by a company to see how a product is doing. Fair?

A. Yes, sir. It's kind post-market guide.

Q. It's on the market a way of kind metaphorically putting their ear to the ground and learning, identifying other issues going on, right?

A. Yes, sir.

Q. That's a good thing; right?

A. Yes, sir. I agree.

Q. So if you look at the field assessment for the Advantage Fit --

A. It's required, too, besides being a good thing.

Q. Required. I'll take that. Ms. Roberts, could you pull up the date Exhibit 473.

So to orient the jury then 2008 is when the Advantage Fit was introduced; right?

A. Yes, launched.

Q. Yes. Launched. And this identifies the sales and it identifies the complaints; right?

A. Yes, sir.

Q. Page 3 of 8?

A. Yes, sir.

Q. If you could blow up the sales there.

So this tells us that the Advantage Fit in the first six months had 5437 units sold. And it has 11 complaints; right?

A. On this table, yes, sir.

Q. Yes. And that's less than 1 percent, isn't it?

A. Based on sales, yes, sir, but that's not always the best way to measure that.

Q. All right. And the threshold that you were describing earlier with counsel there was a threshold here he have 5000 parts per million; right?

A. Yes.

Q. We were substantially below that; right?

A. I believe so, yes, sir.

Q. The conclusion of this field assessment for the Advantage Fit is -- let's go to the top, evaluation of possible relevance to safety. So the conclusion of this field assessment is stated here, among other things the Advantage Fit products have consistently maintained a low complaint rate. I read that correctly; right?

A. Yes, sir.

Q. And go to conclusion, if you would, Ms. Roberts. The conclusion here from this field assessment of the Advantage Fit, Advantage Fit family of

products have met the PPM requirement of less than 5000 parts per million total. The complaints were independently reviewed to assure the events were independent and no single failure mode to was dominant or trending upward. The product continues to perform safely as expected. I read that correctly?

A. Yes.

Q. So that's what the field assessment was of the Advantage Fit?

A. Yes, sir.

Q. Now, I want to talk about and I will offer at this time, Your Honor, Exhibit 473?

THE COURT: I assume there's no objection?

MR. THOMPSON: No objection, Your Honor.

THE COURT: All right.

BY MR. KEENAN:

Q. I want to ask you about the field assessment for the Polyform, Dr. Parisian, permission to approach. Exhibit 1317, there was a field assessment for Polyform, as well; right?

A. Yes, sir. This was 2006.

Q. Yes. So this is a field assessment for the Polyform and the Polyform was the mesh be used in the

Pinnacle; right?

A. Yes.

Q. And this field assessment reflects that there were, in this time period of August 22nd, to April 10th, approximately 6 months, there were 921 units sold and how many complaints, Doctor?

A. 22.

Q. Well, I have zero on mine?

A. I'm looking at the -- that's the Advantage, yes, sir, where are you?

Q. Complaint total?

A. Complaint total. It says zero there. Yes, sir.

Q. So 920 units sold, complaints zero.

Go to, Ms. Roberts, go to the bottom of page 4 of five.

So defendants would offer Exhibit 1317?

THE COURT: If there is no objection they're admitted.

MR. THOMPSON: No, Your Honor.

BY MR. KEENAN:

Q. Can't be better than zero, can you, Dr. Parisian?

A. Well, that's the number. It depends in terms of how you're actually gathering that information and what the Polyform is being used for. So it really was a major use of it. So zero, rare events are not going to occur in that sales.

Q. Let's talk a little bit about the Pinnacle 510k submission.

A. Yes, sir.

Q. You have that in front of you; right?

A. Yes, sir.

Q. Now, Doctor, the Pinnacle included the Polyform mesh and the Capio; right?

A. It wasn't asking clearance for the Capio, so can you restate your question? I'm not sure -- the Pinnacle was for the mesh -- the Pinnacle was for the Pinnacle mesh and there was a discussion of Capio in the 510k.

Q. Let's go to the very -- let's go to the third page of this document here, Doctor. Go to device description.

I heard you discuss with counsel the Capio, and whether the Capio was appropriately described in these -- in this submission. With me so far?

A. I'm not sure where your third page is. Do you have a Bates number?

Q. Yes 56?

A. 456.

Q. Yes?

A. All right.

Q. With me?

A. You're in section nine, is that where you are? 456 page 29.

Q. Page 56?

A. Just 56.

Q. Yeah?

A. I'm not quite sure where you are: I'm not sure where you are want to put it up.

Q. Is the screen on be in front of you Doctor?

A. Yes, sir, your numbers are different that's the issue, you're on page 23 of 49. That's where I was. Our Bates numbers are not the same. Okay. Being I'm on 23 of 49, which is my 450.

Q. It describes device description, with me?

THE WITNESS: Yes, sir.

BY MR. KEENAN:

Q. It describes the currently legally market Capio

open access suture capturing device; right?

A. Yes, sir.

Q. This is obviously the Capio; right?

A. That's statement of Capio. Yes, sir.

Q. This is the Capio. The Capio was a cleared device by the FDA?

A. It is a cleared device by the FDA.

Q. Your criticism this wasn't properly described in our documentation; right?

A. Yes. And there wasn't a picture to show people how they were going to be used. There were pictures, but it wasn't described in terms of the history, the regulatory history and the FDA had to come back and ask the regulatory history. So when you make out a 510k, you include the regulatory history which would be all the 510ks so that the reviewer can go back and pull them up.

Q. But I counted the word Capio used 84 times in this 510k submission. You wouldn't disagree with that?

A. I would not disagree with it, the word Capio is there, the FDA is being told, as an exempt manual instrument.

Q. If you want to just turn Dr. Parisian page 50

of 149, Ms. Roberts page 188, delivery device. This is another place where the documentation is expressly describing the role of the Capio with respect to the placement of the mesh; right?

A. I wouldn't say it's precisely describing it. It does say the word Capio, but in terms of marketing claims that it was going to increased safety and it was going to be a trochanter implantation, that information is not being given to the FDA.

Q. And indeed, Doctor, if you could go to page 69 of 149, or also Bates 106. There's, as part of our submission, there's a diagram of the Capio; right?

A. In this submission. Yes, sir.

Q. Okay. And we could go find lots of other places where the Capio is ostensibly described defined in here, illustrated; right?

A. I wouldn't use ostensibly. The word Capio and Capio does exist. The FDA questioned where Capio came from in subsequent 510ks. So it isn't clearly placed in there.

Q. You don't think this is clear?

A. No.

Q. Go to Bates No. 75, which is page No. 38 of one

02:29:03 49.

02:29:19 A. You mean the MS -- the material safety -- yes.

02:29:24 Q. So the MSDS were obviously submitted to the FDA; right?

02:29:28 A. Yes, sir.

02:29:28 Q. The MSDS was the medical caution statement; right?

02:29:32 A. Yes, sir.

02:29:32 Q. And that's required because the surgical mesh guidance document says manufacturers have to do that; right?

02:29:39 A. Not necessarily. They have to provide the FDA a history of where the resin came from, the materials that are used for the proposed mesh.

02:29:48 Q. Okay.

02:30:13 (Pause.)

02:30:14 BY MR. KEENAN:

02:30:16 Q. So I know the jury has seen this a lot. But this is a Material Safety Data Sheet that was submitted as part of the Pinnacle; right?

02:30:24 A. Yes, sir.

02:30:24 Q. Now, there was a Material Safety Data Sheet that was also submitted as part of the Advantage

submission; right?

A. Yes, sir.

Q. The MSDS that was submitted with the Advantage did not contain the medical caution language; right?

A. That's correct. It was an older -- it was an older version.

Q. Right. So the version that was submitted with the Advantage did not have the medical caution statement. The Material Safety Data Sheet that was submitted with the Pinnacle did?

A. It didn't have a caution statement, but it said what it was intended for the Advantage and it said nothing about a medical device. It actually had similar information. These are both already cleared meshes, so the FDA reviewer is not, by having a history, this is not really the schedule part of the 510k.

Q. The MSDS is the same for the Advantage and the Pinnacle?

A. Yes, sir.

Q. I mean the Marlex; right?

A. Marlex mesh is the same for both, but they are both cleared. So the company can cite already cleared product. So the MSDS isn't the essential part of the

510k review. It's basically a manufacturing issue under 21 CRF 820 that the materials are suitable for what the intended use is. This isn't part of a 510k review.

Q. In any event, the same Marlex provider, the language changed between them, Advantage submission and the Pinnacle submission; right?

A. In that caution that caution was added. The difference between with the two is that the Advantage actually had an MSDS sheet that was for the Marlex resin, which is HDX 030-01. This says all polypropylene mesh caution.

Q. This is the caution statement that was part of the submission for the Advantage I wanted to show to you; right?

A. Right. And this is 1997.

Q. Now, I want to talk a little bit about the exchange between the FDA and Boston Scientific with respect to the Pinnacle. Okay, with me?

A. Yes, sir.

Q. So the FDA had questions about the 510k submission that Boston Scientific submitted for the Pinnacle, didn't it?

A. Yes, sir.

Q. Okay. And there were letters written in the Fall of 2007 about Boston Scientific's submission; right?

A. Yes, sir.

Q. And, Ms. Roberts, if you could pull up September 5, 2007, letter from the FDA, and you went over this briefly with Mr. Thompson. But the FDA described that they had concerns about the safety of the Pinnacle; right?

A. Well, they wanted additional information, yes.

Q. Why don't you right here, Ms. Roberts.

So the FDA is writing Boston Scientific and saying we have -- these new shapes have the potential to raise new questions of safety and effectiveness given that the surgical procedure for implanted pelvic floor may not be equivalent for surgical procedures used for placement of Pinnacle devices; right?

A. Yes, sir.

Q. This was not a FDA asleep at the switch rubber stamping our submission?

A. I have never said it was FDA asleep.

Q. You said these are typically engineers, not doctors; right?

A. That is true.

Q. These are medical questions that the FDA is raising; right?

A. Not necessarily. That's an engineering type question, mechanics were putting something in. There are doctors that they could ask a question about. I was one of those types of doctors that they would ask consulting. That's not necessarily a medical question.

Q. In any event, we can agree that the FDA is raising new questions of safety and effectiveness; right?

A. Or asking the company, have they considered that.

Q. Okay. Ms. Roberts, go to the next paragraph.

So the next paragraph goes on: The FDA has received several hundred complaints, including five deaths related to surgical meshes used had in gynecological surgery, these reports include patients experiencing that adverse events such as mesh erosion, intrusion, infection, abscess formation, sepsis, as well as organ and vessel perforations and post-operative relief, hematoma and incontinence. It goes on.

And they tell Boston Scientific, please provide

information that support your hypothesis that the Pinnacle pelvic floor repair kit will be a safe and effective device that avoids the adverse events cited above. That's what they ask Boston Scientific to do; right?

A. Yes.

Q. At this time in September of 2007, Boston Scientific did not have a pelvic floor kit on the market; right?

A. A that's right.

Q. Johnson and Johnson had a kit on the market; right? Ethicon?

A. I know AMS did.

Q. AMS, other manufacturers had a device on the market. Boston Scientific did not; right?

A. That's correct.

Q. These adverse events that the FDA is writing us about are not Boston Scientific devices; right?

A. That's correct.

Q. All right. Now, this is the FDA doing its job; right?

A. Yes.

Q. They are the protecters of public health;

right?

A. Yes.

Q. And so they are raising questions and they're putting the obligation of Boston Scientific, you need to show us that you -- we will have a safe and effective device that avoids the adverse events cited above; right?

A. Right. They were relying on Boston Scientific to be the expert to have done development of such a product.

Q. And they are telling Boston Scientific that that --

A. They're saying what the risks are.

Q. Just a minute. Such safety and effectiveness may include a clinical evaluation of your device; right?

A. Yes.

Q. Now, Boston Scientific replied to this, didn't they?

A. Yes, sir, they did.

Q. Boston Scientific sent a reply and had information about the Pinnacle and the Capio; right?

A. Well, let's see what you have.

Q. Okay. Let's go to the October 3rd, 2007,

letter. And let's orient the jury here. So we have the FDA on September 5, 2007, says please provide information that sports your hypothesis that the Pinnacle pelvic floor repair exit that will be safe and effective that avoids the adverse events cited above; right?

A. Right.

Q. And Boston Scientific replied and, Ms. Roberts, I would say let's go to --

A. They also included they wanted a clinical trial, or they suggested a clinical trial.

Q. There's no question pending.

A. Okay.

Q. Why don't you go to page 8 of this letter. And, Dr. Parisian, this is Bates No. 233, which I believe is part of the Pinnacle submission?

A. Your Bates change. What page?

(Pause.)

BY MR. KEENAN:

Q. So October 3rd, we respond and let's -- Bates No. 233?

A. Your numbers are not the same as my Bates numbers are the issue.

Q. Go ahead and take a minute. That's fine.

(Pause.)

THE WITNESS: I don't know that the amendment is in this packet. It might be.

BY MR. KEENAN:

Q. Doctor, if you would like, you can look at the screen in front of you. That has the document there. So are you ready?

A. Okay.

Q. So what the Boston Scientific does, they repeat the FDA question; right?

A. Right. This is what we looked at earlier this morning.

Q. Well, you didn't look at all of the document. Let's go through all of it?

A. Okay.

Q. So Boston Scientific repeats the question. We've been over it. Let's go to Boston Scientific's response. Ms. Roberts, go to the second paragraph here.

Now, one of the things that Boston Scientific points out is that the predicate devices used different types of delivery devices; right?

A. Yes, sir, trocars.

Q. Trocars, the jury may not appreciate what a trocar is, but I have an example. A trocar is something that looks like this; right?

A. That's one type of a trocar.

Q. This is the Prolift; right?

A. Right, a trocar in general can have different structures.

Q. Just generic trocar?

A. A trocar is a tube that you would used to insert something into the belly, then you have a trocar and feed something through it.

Q. Yes. This trocar, this is one of the predicate devices the Prolift right?

A. Yeah.

Q. This is not a Boston Scientific device; right?

A. That's correct.

Q. So the trocar involved the doctor sticking this device through various parts of the body to delivery the mesh, the pelvic organ prolapse mesh; right?

A. Yes, but the FDA they're talking about trocars in general. Some trocars you can actually see, cameras they can put through. You're telling the FDA trocars, trocars could be a lot of different things.

Q. I'm just talking about this one, there's no camera on this?

A. The response to the FDA reviewer trocar would have different meaning.

Q. Dr. Parisian, it's true that the FDA identified certain risks with are the trocar and blind passages through the body; right?

A. Right, and there are certain risks.

Q. Okay. And indeed, Ms. Roberts, if you could, the trocar it notes here, this is what we're responding to the FDA is advanced blindly in the direction of the desired anatomical landmark. That is identified through palpation by the physician's finger from within the vaginal incision, right?

A. That's what it states.

Q. Furthermore, it states that the physician aims and advances the trocar towards his/her finger to create the needed path for mesh delivery; correct?

A. Yes, sir.

Q. I have an illustration here and I want to ask if you were to agree with me that this illustration shows delivery routes for a trocar based system versus Capio. Would you agree this is accurate question of

incision points for a trocar based system like the Gynecare Prolift?

A. You're talking about multiple places where trocars are being put in. You've taken all of them and put them on one picture.

MR. THOMPSON: Your Honor, could I inquire that is not part of the filing, this is a prepared slide; is that right?

MR. KEENAN: Yeah, I prepared it.

THE WITNESS: This isn't in the --

BY MR. KEENAN:

Q. Does this reflect the number of passages that a trocar would use like the Gynecare Prolift?

A. It's a lot of -- they don't have that many incisions in a delivery but, yes.

Q. Do you know how many incisions are used with a Gynecare Prolift?

A. Well, it depends you have the anterior, the posterior the total. You can include all those. Just because the number doesn't mean it's safer to have only one in the central, because you're going to be plucking around. No. In terms of an incision, that doesn't mean that it's less safe with trocars.

Q. Do you know how many incisions are made with a Prolift -- a Gynecare Prolift delivery system?

A. It depends on which ones is going to be implanted, anterior, posterior, total.

Q. Could be as many as six incisions, right?

A. Right, the trocar makes it more controlled than the Capio.

Q. The Capio, in contrast to that, has one incision; right, one?

A. That doesn't make it safer.

Q. I'm just asking you does it have one incision?

A. What you draw on here. Yes, sir.

Q. So one versus as many as six?

A. That's just a number, but there's reasons why you would use the other trocar. I'm not the surgeon to talk about this, I don't think.

Q. I appreciate you're not a surgeon?

A. Yeah.

Q. Let's go to the next page. I really want to move on and get past this. Our response to the FDA on the next page, if you could go there, Ms. Roberts, notes the difference to the FDA of the incision sites between our predicate devices and the Capio; right. So it says

in contrast, the Pinnacle pelvic floor repair kit uses Capio to deliver the mesh to desired anatomy. The physician can avoid any blind passage through the pelvic floor anatomy with the use of a Capio device. The risks of organ vessel perforation, as well as hamartoma and post operative bleeding increases with each additional blind passage through the skin and anatomy in predicate procedures. What they're saying the predicate devices have a different tool that actually insert the mesh than the Boston Scientific device?

A. That's what you're telling engineers, yes, sir.

Q. The risk due to these blind passages is eliminated in the Pinnacle pelvic floor repair kit because of the absence of such blind trocar passages; right?

A. That's what they stated.

Q. Additionally, no skin incision is required to deliver the device, only the vaginal incision the absence of a skin incision is expected to reduce the risk and sepsis to the. Patient that's what we told the FDA; right?

A. They told the FDA that, but there's no data to support any of that.

Q. And the FDA cleared the Pinnacle a month later?

A. Yes, they did. Because they expect you, as the company, to be the expert in this product and that information has no support at all.

Q. The FDA determined that our device was substantially equivalent to the existing devices on the market; right?

A. Based on what your representation was that there was nothing novel or new about the product. And that's not correct.

Q. Okay. And the FDA's questions to us that were raised in the September 5, 2007, letter about the hundreds of complaints in asking us please provide information to support your hypothesis that the Pinnacle pelvic floor repair kit will be a safe and effective device that avoids these adverse events cited above, the FDA cleared the device; right?

A. Based on Boston Scientific's hypothesis. That means it's not been shown.

Q. All right. Let's talk about the field assessment of the Pinnacle. We've already discussed the field assessment of Advantage Fit; right?

A. Yes, sir.

Q. We discussed the field assessment of the Polyform; right?

A. Yes, sir.

Q. Let's talk about -- and we replied on October 3rd and it was cleared; right?

A. It was cleared.

Q. Now, let's talk about the field assessment. Ms. Roberts if you could pull that up, please.

Now, you spent quite a bit of time talking about this, or sometime talking about this with Mr. Thompson?

A. Some time, not quite a lot.

Q. Fair enough. But this document tells us quite a bit of information about how the Pinnacle was performing in the first year; right?

A. Yes, sir.

Q. Okay.

A. Or what Boston Scientific knew.

Q. We know from this document, Ms. Roberts, if you could pull up the total sales.

We know from this document that the total sales of the Pinnacle in the first year was 5409; right?

A. Right. Which isn't really that much.

Q. We also have total complaints, according to this, were 191; right?

A. Yes, sir.

Q. So the percentages, just doing a rough calculation the percentages of complaints over sales is 3.5 percent; right?

A. If you calculate on sales as opposed to used, yes, sir.

Q. If an attorney told this jury that are there were 34 thousand adverse events during this reporting period, that wouldn't be correct, would it?

A. I don't believe that's what they would have got from this document. It's parts per million. It's the company's calculation.

Q. And parts per million, we'll talk about that in just a minute. Without getting into the math, just the basic numbers we knew from the field assessment, 5409 sales and 191 complaints?

A. Those were the sales yes, we don't know how many were actually implanted.

Q. That number can actually be too high if you take the number of complaints it might be lower than that?

A. Well, for the denominator it actually may be high, that's why that time of a number is used because it will reduce the calculation.

Q. Let's spend about 5 minutes going through this document. All right?

A. Um-hmm.

Q. So this document broke out, Ms. Roberts, if you could go to the next page, page 3 of 34. Blow up this part right here.

Doctor, Boston Scientific broke out these complaints into three categories; right?

A. Yes, sir.

Q. They broke out mesh complaints, suture complaints, Capio complaints; right?

A. Right, and those are acute complaints, yes, sir.

Q. Now, the jury has heard this ad nauseam. This is a Capio complaint; right?

A. Well, it could be, in terms of when you look at the document only one complaint as was assigned to a category. So there could be multiple complaints for one report, but one category was assigned.

Q. All right. And the suture complaint would be

way down here at the end; right?

A. In terms of a physician complaining about the suture, yes, sir.

Q. Yes. So we've got the Capio. And we have the suture; right down here; right?

A. Right.

Q. And both are important, I'm not trying to minimize them. But neither of those two categories involves the mesh; right?

A. Correct. None of these categories are long term, in terms of the woman's risk.

Q. Okay. So if you look, break out the categories and you accept Boston Scientific's numbers here at face value. You have suture complaints, and you have Capio complaints equals 107 of the total complaints numbers or 1.9 percent; right?

A. Yes, sir.

Q. The Capio, they had some difficulties with the Capio; right?

A. Yeah.

Q. Won't catch suture, carrier break, won't load. The suture had dark separation and suture breaks; right?

A. Right. In the middle of a surgical procedure

are significant.

Q. I'm not trying to minimize them. Neither had to do with mesh, per se; right?

A. The way it is categorized by Boston Scientific.

Q. We know, don't we, Doctor, because we discussed this that Boston Scientific did a design change to the suture and how it inter faces with the Capio in March of 2008 to address this; right?

A. Yes.

Q. And they addressed this for dark separation, suture breaks, and dilator bunching; right?

A. That was part of a Capio action. I think the Capio was independent. They had two different Capio, didn't they.

Q. In fact, the Capa, which was a change in manufacturing was successful, was it not, in fixing this problem; right?

A. That particular problem.

Q. Yes. I'm going to show you Defense Exhibit 363. Permission to approach?

THE COURT: Certainly.

BY MR. KEENAN:

Q. Ms. Roberts, if you could pull up Exhibit 363

at the top here right here.

So this reflects a Capa in March of 2008, for complaints have been received for dart separation resulting in this Capa and there were changes made to the Capio and the suture to address this, and it was successful, wasn't it?

A. Yes. And those are immediate problems that could be identified in the OR.

MR. KEENAN: I would offer at this time Exhibit 363.

THE COURT: Admitted.

BY MR. KEENAN:

Q. Doctor, then if we go to now focus on the complaints for mesh in this document, the mesh complaints were 84; right?

A. Yes, sir.

Q. And that would be 84 out of 5409. And in the field assessment it has factual summaries of each complaint; right?

A. It does if they are different ones.

Q. Did you see in all of the field assessments a single complaint for folded mesh?

A. For folded mesh, I don't recall. Do I have

that document? Is it here?

Q. No. It's in the field assessment. Did you see any complaints for folded mesh?

A. I think there were folded mesh because the physician was upset about the folded mesh, not for folded mesh in patients.

Q. Did you see any complaints for folded mesh in patients?

A. In the field report?

Q. Yes.

A. I need to pull that up. I don't remember.

Q. If you'd like to take some time you're certainly welcome. I've been through it, I didn't see any. Now, I'm an advocate for Boston Scientific?

A. I don't recall what meshes were.

Q. Just to move things along. No recollection. What about bunched mesh. Did you see any complaints by physicians by bunched mesh?

A. I know the dilator issue was a issue with bunched mesh and bunching of the dilator.

Q. Do you know what the dilator is?

A. Yes, that.

Q. It's this?

A. Right.
Q. This was getting bunched, right?
A. Right.
Q. Not this?
A. Right.
Q. My question is bunched mesh?
A. I'm not sure where you're talking about in the field report, where you're asking me these questions. That's why I wanted the document. Do I have that document? Is it from this morning?
(Pause.)
BY MR. KEENAN:
Q. Here's a copy of mine.
A. Okay, thank you. All right. Now I'm better.
(Pause.)
BY MR. KEENAN:
Q. This field assessment has very quick summaries of each complaint; right?
A. Yes.
Q. And recognizing that they're not lengthy, it does have descriptions of what the doctor called in of what they complained about; right?
A. Right.

Q. And so an example would be it was reported to Boston Scientific that during an anterior repair using the Pinnacle, the bullet broke off from the mesh leg and was had was fired through the patient's left arcus tendineus and was later located. That's the kind of thing that might be included here in this summary?

A. Yes, that's awful to have happen in the OR.

Q. My question: Did you see anything when you look through this with bunch mesh --

A. Okay. Well, let me look there's a whole list here. Bunched mesh...

(Pause.)

THE WITNESS: I don't recall bunched mesh. I see a lot of the other things worse than bunched mesh.

BY MR. KEENAN:

Q. I'm focussing on bunched mesh. No. What about wadded mesh?

A. I see a lot of injuries. I don't see that they've broken the mesh injuries down to those. They're using the physician's complaint, which is not those words. They're using other words that would be types of complaints you'd get if you get bunched and wadded mesh, erosion, they're using words like adhesions, clinical

dysphrenia, infection, erosion they are not using folded and bunched.

Q. My question, did you see the word folded bunched mesh?

A. No, I see patient injury.

Q. Did you count how much erosions there were?

A. No, I didn't specifically.

Q. I did. And there's ten.

A. This is only in one year of use. That's significant.

Q. Let's see. Outside of the Capio issues which we've talked about after July of 2008 when a Capio fix was instituted, you did not see the same type of trending with regard to the Pinnacle, that's true, isn't it?

A. With the Uphold?

Q. No, the Pinnacle?

A. What when are you talking about.

Q. Outside of the Capio issues after July 2008, when those were fixed you did not see the same kind of trending going forward with the Pinnacle, did you?

A. No.

Q. All right. Let's shift gears. I'm winding

down here. I've got a few other things I'm going to talk to you about.

MR. KEENAN: Just a minute, Your Honor, to get organized.

(Pause.)

BY MR. KEENAN:

Q. There was a time after the Pinnacle had been cleared where the FDA exchanged correspondence with Boston Scientific about the material safety data sheet; right?

A. You mean for the Uphold, when they were getting the Uphold cleared.

Q. That's right. And this was in July of 2008; right?

A. Yes, sir.

Q. So the Pinnacle had been cleared. It had been introduced about January 2008; right, thereabouts?

A. Yes, sir.

Q. So the FDA identified the caution statement of the Material Safety Data Sheet, the same data sheet we submitted with the Pinnacle; right?

A. Yes, sir.

Q. And the FDA wrote Boston Scientific and said?

A. What about this.
Q. What about this, right?
A. Because the FDA couldn't do anything about it.
Q. Another example the FDA reading the submissions, identifying language that it was new, and engaging Boston Scientific; right?
A. Right. Trying to ask what the company had done about it.
Q. Okay. And your testimony is that Boston Scientific handled those inquiries appropriately; right?
A. Well, the FDA wasn't able to do anything when the company came back and said it has been historically used with the same indications in the Nineties. So the FDA can't do anything.
Q. Let me try this again.
You agree that Boston Scientific handled the exchange with the FDA appropriately on the MSDS; right?
A. Yeah, I didn't say anything about Boston Scientific other than the Boston Scientific should have been aware of the risks. The FDA's hands were tied for a mesh that had been used since the Nineties.
Q. Okay. So let's go through these real quickly, this exchange, okay. Do you have it there, Doctor, do

you have the exchange?

A. I don't know if I do. Is it the July 17th, 2008, response, is that it?

Q. It's July 18th we're going to talk about your July 17th document in just a minute. Yes?

A. I don't have that.

Q. Let me lay the foundation here, Doctor. You're looking at the July 18th letter from Boston Scientific to the FDA; right?

A. Yes, sir.

Q. Okay. This, Your Honor, is actually its own exhibit number, it's Exhibit 68. So I would offer this at this time Exhibit 68?

THE COURT: Hearing no objection, it's admitted.

BY MR. KEENAN:

Q. Let's go, Ms. Roberts, to page 22 of this document. Do you need a copy, Doctor?

A. If it's going to be longer than this, yes, I'd like a copy.

Q. Ms. Roberts, if you could go to page 22.

Here we go, Doctor?

A. Thank you.

Q. Go to the top of the question.

So the FDA, July 2008 is asking the question of Boston Scientific about the medical application caution statement; right?

A. Yes.

Q. And they're quoting it expressly here; right?

A. Yes, sir.

Q. Please provide a rationale why you're mesh material is safe for use as a permanent implant contrary to what is listed in the MSDS provided for the Marlex material; right?

A. Yes.

Q. And Boston Scientific replies for two-and-a-half pages; right?

A. Right.

Q. And included in the response is a copy of the contract where Chevron is agreeing to sell us this with the express understanding that we're using it for an implantable device; right?

A. Yes, but that's not the key paragraph. If I was an FDA reviewer --

Q. Doctor, I'm just asking if the document says that?

A. Yes.

Q. Furthermore, we have identified safety testing; right, bottom of that page? And we also describe a rabbit implantation study, the next page, and go to the last page, if you would. And the Marlex -- you were saying something about the typo of the Marlex type. This is the right number; right.

A. Yes, sir. This is same mesh that was in Trelex and Advantage.

Q. Right. Right. And would it be fair to say that in 2008 the that the FDA would have quite a bit of knowledge about the use of Marlex mesh as an implantable device?

A. Well, I can't say what the FDA thinks or knows, but the issue is that's why I referred you back to the first paragraph. And this all goes back to the 1992 Trelex mesh 510k which has been the basis for all the biocompatibility testing for the mesh after 1992 by the company. So they had the 1992 data, and everybody has been able to reference that since 1992. The issue is that this product has been marketed since 1992. So FDA can't do anything.

Q. Well, the FDA certainly has knowledge and

information from the medical device reports you were describe for us earlier about how Marlex is performing in patient populations, fair?

A. No. The FDA legally cannot take any action when the company comes in that very first paragraph and says it's been used for an implant since, you know, long history. That means FDA hey, keep your hands off it. Then FDA would have to go back and look at everybody else's mesh. So FDA is going to have to back off. Use as an implant can be referenced by a company and they're saying we've had a long history of use. So that's what the bulk of this document is about.

Q. I don't want to revisit old topics, but we know for a fact the FDA wrote us in 2007, and they were expressing concerns about safety issues with the predicated devices; right?

A. Yes, sir. No, not with all predicate devices with the Pinnacle and with the -- the Pinnacle device because if you use TVT and Prolene, they actually had been approved products. They have a totally different history.

Q. The FDA obviously had information about other products, not Boston Scientific products, in September

of 2007; right?

A. There are other products that are cleared, but they really can't do anything to a product that's been on the market for years.

Q. Okay. In any event, Doctor, the FDA got this information and this product was cleared; right?

A. Yeah. There was nothing the FDA could do about the Marlex. So they cleared it.

Q. And they the Uphold was cleared with FDA's full knowledge and information of the medical safety data sheet process there; right?

A. Yes, sir.

Q. Couple of things and then I'll be done.

In this time period of July 2008, the FDA was, in fact, talking to Boston Scientific a fair amount about this Uphold submission; right?

A. They weren't talking. All we have are the letters, there were some e-mails. There was a meeting, I believe, November 6th, that was of the Pinnacle. I don't know if they were talking.

Q. Let's go to Exhibit 665. No. I'm sorry. I want 1316.

Doctor, in your review of the documents as part

of the regulatory exchange between Boston Scientific and the FDA, you'd want to know all the correspondence and whatnot between the two companies; right?

A. Yes, sir. And that would come from your company.

Q. And so I'm going to offer at this time Exhibit 1316, which is a July 8, 2008, e-mail from the FDA?

A. From Jiyoung Dang, PHD, biomedical engineer.

Q. Okay. So this would be -- could you pull that up there. So this would be within 2 weeks of the exchange that we've already marked and talked about regarding the questions FDA had with regard to the up hold; right? Those were July 18th and this is July 8th; right?

A. Yes, sir.

Q. And for the jury's orientation KO -- KO 81048, that's a term that references a particular filing number; right?

A. Yes, 510k.

Q. That's a 510k and I'll ask you to assume that number is the up hold that we've been talking about; right?

A. Yes, sir.

Q. So to reflects a call with the FDA for -- to request additional information on that submission; right?

A. Well, a call with one reviewer.

Q. Okay. But he's a biomedical engineer; right?

A. Well, he's a reviewer.

Q. Okay. Is he not capable by himself of reviewing this?

A. I don't know, this is one call with one engineer.

Q. Okay. And I will also ask you about a different communication. If you could pull up Defense Exhibit 665.

In this same time period, in fact, the day before this meeting with the FDA --

A. No, don't call it a meeting. They're going to have a call with a group of people from the company and one engineer.

Q. A meeting, a call. They exchanged information, fair enough, Doctor?

A. Well, this is the day before.

Q. Right. Let's pull this up. Day before the

call with the FDA this is Exhibit 665 and I will offer it at this time?

MR. THOMPSON: Your Honor, this is obviously hearsay and I don't want to slow everybody down, he's already displayed it. I don't want to slow it down. This is really not a proper document to put in front of Dr. Parisian.

MR. KEENAN: It's a notice to the company. Do you want a sidebar?

THE COURT: Are you --

MR. THOMPSON: That's all I wanted to say, Judge.

THE COURT: You're not pursuing your objection.

MR. THOMPSON: Yes, Your Honor.

THE COURT: All right. Why don't we take our afternoon recess at this time.

(The jury left the courtroom at 3:09 p.m.)

(The following sidebar conference was held.)

THE COURT: So the objection is hearsay. What's the exception, or is it not hearsay?

MR. KEENAN: It is noticed to Boston Scientific consistent with the testimony of this Doreen Rao that the medical caution statement had nothing to do with any

health or safety issues, but it rather was a precautionary matter and the that the alternative responsibility is in Boston Scientific's hands. This is notice to Boston Scientific in terms of their good faith in proceeding ahead with the Marlex resin. There has been ample testimony by plaintiffs that it represented some safety issue that we need to do follow-up, we needed to do further investigation and this is just additional information, right the critical time in July of 2008 with the FDA it was reviewing a document they put into evidence with the Uphold that the MSDS did not raise any issues of safety and Boston Scientific's information about the biocompatibility testing was sufficient.

THE COURT: Is there going to be any witness that can authenticate this document so that it's not hearsay within hearsay?

MR. KEENAN: It's been on our exhibit list. They didn't object to it on any basis. Not that they would waive it, but there's no objection to being authentic for sure. We can have a limiting instruction to the jury this can only be considered for the purposes of notice to Boston Scientific, but this goes to the

core of the case.

MR. THOMPSON: Judge, Mr. Keenan, every bit of his argument is that it's not notice, it's being offered for the truth of the matter that they were reassured by some statement from FDA some type and there's no witness to put this in. I mean, I lived with the -- with the e-mail that talked about a meeting in the future because it seems irrelevant and harmless but this is actually this is offered for the truth of the matter the idea that Boston Scientific needs notice of anything is kind of silly. This is offered for the truth of the matter. It's a hearsay, it meets no exception. Certainly the interaction with the FDA we've agreed that they have a right to put that in, that's what we're wrestling with this sort of effort to bolster using inadmissible testimony is just incorrect. We object to it.

MR. KEENAN: He raised in opening that this represented some sort of red flag that we didn't investigate, we didn't do anything we just kept our head in the sand and this is good faith on the part of Boston Scientific employees of reaching out and soliciting information right at the critical time of when the FDA was meeting and discussing with this, and this -- it

shows Boston Scientific's state of mind which is very much within put in doubt about whether or not we were using due care in acting as a reasonable company. That's exactly what this goes to.

THE COURT: What I'm going to allow you to do is not put this document itself into evidence. The document does contain hearsay. Bum I am going to let you ask an appropriate witness, I don't know whether this witness is appropriate or whether it would be more appropriate for a Boston Scientific whether or not they received information from FDA of some type and they need to talk about how this even this correspondence was engaged and whether they said that you didn't need to do anything else. But the document itself goes beyond notice. The document itself goes to whether or not Boston Scientific should have done something additional, which is relevant and it would be admissible if you had a sponsoring witness.

MR. KEENAN: I'll use it with my FDA witness then. I'm almost done, by the way, I only have about 3 minutes left.

MR. THOMPSON: Great.

THE COURT: We're in recess.

(Sidebar conference concluded.)

(A short recess was taken.)

THE COURT: Is there a chance we're going to get Dr. Dunn on the stand today.

MS. FITZPATRICK: There's a chance, Your Honor I don't know about the documents -- I'm happy to deal with them at sidebar. I think once the foundation is laid it's going to be much more obvious what's going on I'm not even sure you're going to have objections to them.

MR. ANIELAK: Can I alert the Court what my objection are? I object to the use of the term -- can we do it at sidebar because the witness is in the courtroom.

THE COURT: Yes.

(The following sidebar conference was held.)

MR. ANIELAK: Dr. Dunn is an engineer. This is a nonmedical person, who is a nonmedical person thousand times. I object to the uses of the term sharp to describe the edges of the mesh. It doesn't apply that there are somehow going to be injuries by the plaintiff. He didn't feel the edges of the mesh using that term is prejudicial, that's my first issue. We object to the

term sharp or using the term sharp to describe the edges. It does connote a medical condition, gives a presentation to the jury that somehow she was injured by the edges of the mesh. That's our first objection.

The seconds issue goes back to the MSDS, again at this point this is cumulative in terms of what the MSDS says. Dr. Guelcher went through the whole thing on oxidation and the third one is it's also cumulative and outside this expertise in terms of analyzing the medical issues.

MS. FITZPATRICK: On the use of the term sharp, that is based on directly his expert report that he got deposed on. It says oxidation not about the clinical implications about that for what he's going to say that the device does have regular jagged sharp edges and that is something that Boston Scientific was required to consider under appropriate design theories, but he's not going to make any clinical correlation to any injury to Ms. Barba, or any other woman with that, and it is specifically disclosed with that specific description.

The second was MSDS, we're not going back to oxidation, but we are going to go to what a reasonable manufacturer in using a proper design process have

considered the medical application caution cleared on it's risk analysis, and taken action on it and Boston Scientific did not, which again goes square to his design process, but I'm certainly not repeating what it is that Dr. Guelcher had said on oxidation. The third is the product field assessment which was disclosed. Once again, in his expert report, he was also disclosed in his expert report as saying that the sixth concept of a product design is to do product field assessments and to be monitoring them and that Boston Scientific did not do a proper field assessment and than they did not take the information that they knew of and gathered post-marketing and post-sale and incorporate that into the risk analysis document which is supposed to be a living document that exists and exchanged based on new information for the entire lifetime of the product. So all of them were disclosed, none of them were inclusive.

THE COURT: First of all, I'm finding that the term sharp is not a medical term, but I think you need to make that very clear with your witness, that he is not opining as to whether that property would effect the body in one way or another. You can simply describe it using a lay term. And if I recall, the main objection

to the other two topics was on the basis of cumulative evidence.

MR. ANIELAK: Partially yes, Your Honor and detail getting into the medical aspects of a medical device. You made it very clear last week that he's not an expert on medical devices, and I don't want to venture what a medical device company should, or should not be doing with regard to monitoring medical devices.

THE COURT: So he can testify then from an engineering standpoint as to product design, and testing but should not be opining specifically with regard to medical devices.

MS. FITZPATRICK: That's correct.

THE COURT: As we go along with this, if it looks likes the testimony is getting unduly cumulative, there's undoubtedly going to be some overlap, but if it becomes unduly cumulative, then you may assert your objection.

MR. ANIELAK: Thank you, Your Honor.

MS. FITZPATRICK: Thank you, Your Honor you.

(Sidebar conference concluded.)

BY MR. KEENAN:

Q. I only have a few questions left Doctor, I want

to go back to a doctor that you used with Mr. Thompson, and that is July 17, 2008, document which represented some questions from the FDA. And on the Uphold and in particular, Doctor, I want to direct your attention to the questions that Mr. Thompson had for you about the Capio, do you remember those?

A. Yes, sir.

Q. All right. So you and Mr. Thompson were talking about this document and you were describing some of the MDRs for the Capio; do you recall that?

A. Yes, sir. I think I questioned whether this was a draft document or the final.

Q. Yeah. That's what my question is. You don't know whether or not this was a draft or the final version. Fair?

A. I think this one that you gave me was the final version, Exhibit 68. This is the draft.

Q. Thank you. And because, among other things, the date on this July 17th, 2008, is 11 days before the actual letter that was sent to the FDA July 18th; right?

A. Yes.

Q. And this letter includes the same question but a different shorter answer; right?

A. Well -- yeah, it's a different answer.

Q. Okay. But this Exhibit No. 68 would appear to be the actual response to the FDA; right?

A. Yes, sir.

Q. And while we're looking at this, you will admit, won't you, that the time period where they are looking at the Capio MDRs is a time period that really doesn't, it overlaps some, but not entirely with the time period for the field assessment; right?

A. Yes, sir.

Q. This is a two-year period, this is a January through May 2008. And the field assessment was the entire calendar year 2008; right?

A. Yes, sir.

Q. A few other things, and I'll be done.

Mr. Thompson asked you about a letter from some surgeons that you were discussing, and I believe you were describing how this group of physicians was attempting to delay the public health notice; right?

A. No. Their recommendation was that the FDA delay sending it out and hold a meeting instead with the people on the council.

Q. They didn't delay the public health notice;

right?

A. The FDA, no.

Q. It came out after this. And my final document is actually this document, the public health notice.

Now, this is directed to doctors; right?

A. Yes, sir.

Q. Not to companies, but to doctors; right?

A. Yes.

Q. No. 1. No. 2, this is a good thing, is it not, because it wants to make certain that if a doctor is out there using these products and thinks that there's no risk whatsoever, it's telling him, hey, proceed with caution. Fair?

A. It's getting the information out, that's what the FDA is trying to do. I think there's a patient one, too.

Q. That's a good thing?

A. For the FDA to do that? Yes, sir.

Q. And for physicians, too, to get to information; right?

A. Yes, to try to protect public health.

Q. They describe one thousand reports from nine surgical mesh manufacturers; right?

A. Right.

Q. You and I were talking about number of manufacturers that made transvaginal products and there was at least nine?

A. Yes.

Q. And one of them is Boston Scientific; right?

A. Right.

Q. At this time October of 2008, Boston Scientific's first pelvic organ prolapse device the Pinnacle had only been on the market less than a year; right?

A. It began in January, yes.

Q. The FDA notes here that these as of October 2008, were described to the FDA as rare; right?

A. Well, no, the FDA is saying that.

Q. Yeah. The FDA is saying although rare, these can have serious consequences be; right?

A. That's based on the FDA has received. And than one thousand would be from their MDRs.

Q. We don't know what the denominator is, we know it's a thousand complaints, but we don't total number of sales or manufacturer --

A. There's nine manufacturers. We don't know what

the reporting factors are. The FDA is looking for a trend, only the companies would know what the denominators are and with the real complaint numbers are.

Q. And the FDA is telling physicians that among other things, they should be trained; right?

A. Yes.

Q. Be vigilant for potential adverse events from the mesh; right?

A. Yes, sir.

Q. They should watch for complications; right?

A. Yes, sir.

Q. They should inform patients that it's permanent; right?

A. Yes.

Q. And that some complications assertion may require additional surgery; right?

A. Yes.

Q. They're telling the doctors inform your patients about the potential for series complications and be their affect on quality of life, including pain during intercourse, scarring, and narrowing of the vaginal wall; right?

A. Yes, the FDA is telling them.

Q. It says provide patients with the a written copy of the patient labeling from surgical mesh manufacturer if available; right?

A. Yes, sir.

Q. When you and I were talking earlier about sources of information, this is an example of information coming to the doctors about risks and benefits of the transvaginal mesh products they may be using, that has nothing to do with the companies; right?

A. This is outside of the companies. This is FDA has become aware of a safety issue.

Q. Right. So a physician who may be dealing with a company, this is an independent basis of information about risks and benefits that he can factor into his clinical evaluation of a particular patient who may be a candidate for these products; right?

A. If he's aware of that.

Q. Right. Well, this is going to the doctors; right?

A. No, it's on the FDA's website saying dear healthcare providers.

Q. This public health notice did generate quite a

bit of publicity, didn't it?

A. It did. I don't know what physicians are in terms of your daily care, often times something like that is brought to the physician by the sales rep. That would be a normal thing to have happen.

Q. But this obviously was from the FDA to physicians, and physicians who are using these products it's something that they should endeavor to be aware of. Fair?

A. This is what the FDA is saying based on what they received in their reports.

Q. All right. Thank you.

A. You're welcome.

(Pause.)

REDIRECT EXAMINATION

BY MR. THOMPSON:

Q. Doctor, sometimes something happens that you really didn't anticipate. I didn't really anticipate that there would be a field assessment on the Polyform mesh. Do you remember that?

A. Yes, sir.

Q. You actually saw that the Polyform mesh was in 2006, you saw you that it had, like, zero?

A. Right, but it had only 921 units.

Q. Zero. The Polyform mesh is that 15-by-10 centimeter square; is that right?

A. Right.

Q. The Capio, I think they showed a field assessment on that. And it seemed to be kind of low or very low?

A. Yes, sir.

Q. Now, the field assessment that showed the Capio, the suture, and the mesh together, was the Pinnacle device?

A. Yes, sir.

Q. Okay. So the individual components, if the Capio was being used as cleared for which was, as I recall, open surgical with endoscopy, do I remember that right?

A. Yes, sir.

Q. If it was being used for what it's cleared for, apparently it didn't have many problems; is that right?

A. Yes.

Q. Apparently if you used the Polyform in a reasonable size, it didn't seem to have many complaints either?

A. Correct, it's a surgical mesh, yeah.

Q. If you take and you get a very large piece of the Polyform mesh, and you cut it into a special shape, and you put four arms and you implant two arms into the arcus ligamentous and two into the sacrospinous ligament, apparently you get a result that shows six times the expected complaint rate?

A. Right.

MR. KEENAN: Objection. Leading, Your Honor.

MR. THOMPSON: I will not lead, Your Honor.

BY MR. THOMPSON:

Q. Doctor, is that a red flag to a medical device company that they have a serious problem with combining and designing the Pinnacle kit?

A. Yes. It's the design issue, in terms of your 21 CFR 820. That is what the components together are what makes the difficulty and where you're placing it.

Q. And, in fact, the low complaint rates of the individual components, as compared to the very high complaint rate of the kit, doesn't excuse the kit. It should give rise to a higher scrutiny as to safety and efficacy, isn't it?

A. Right. And to try to determine what's the

problem in terms of your design of these products being used together.

Q. Doctor, I think you recall in the MSDS discussion we've kept talking about the -- we talked back and forth about this MSDS disclosure and the Boston Scientific response to the FDA in the Uphold discussion. And we talked about, and here again I'm thankful that the defendant has actually provided me with a real copy instead of that draft copy that we had handed up, okay?

A. Yes, sir.

Q. So we're looking at Defendant's Exhibit 68 now. And we're looking at FDA question No. 8 at page 22 going onto 23.

A. All right.

Q. Have it?

A. I should. Yes, I have it right here.

Q. Go to 22, onto 23. Let me just alert Mr. Keenan, it's my intention to confront her with Goddard 15. Your Honor we need to approach the bench, if that's okay?

THE COURT: Okay.

(The following sidebar conference was held.)

MR. THOMPSON: Your Honor Goddard 15 is the

ISO10993 document which refers to the fact that the improper testing was performed on the guinea pigs. And part of the response to the FDA that was included in the MSDS discussion on this July 18th letter is an assertion that they have done proper testing and that they have done proper testing, and it's proper for the last 10 years. We think the door has been opened to permit Dr. Parisian to see, and to note for this jury that, in fact, that statement is not correct.

MR. KEENAN: I did not mention the word bio capability. I did not mention the word sensitization. The fact that the FDA cleared the device, does not open the door. We heard that it's not on the exhibit list, not on the guidance list not previously disclosed, completely outside anything she talked about she opened the door. She talked about it before. She opened the door about the FDA not knowing, you know, all of the various opinions. I have to challenge that. I didn't open the door to it. This is sensitization of mice, of mice I did not talk about biocompatibility. I didn't raise any of those issues. I didn't raise the word desensitization. So no door has been opened. This if opening a door is challenging an FDA's opinion that we

in fact got clearance and I'll plead guilty to that, but that's the core of the case has nothing to do with this document.

THE COURT: Seems to me you can use this with one of the Boston Scientific witnesses, can you not.

MR. THOMPSON: If one comes, I certainly could.

MR. KEENAN: It was used extensively with Jim Goddard to testified about this document by video. This was the very document --

THE COURT: Again, I think Boston Scientific was pretty scrupulous in limiting the cross and I don't think it opened the door to this exact document.

MR. KEENAN: He wants to use this Canadian Regulatory document and this has been the subject pretrial motions noise and be sustained this is Canada not allowing the clearance of the Pinnacle on May 13th 1 day after Ms. Barba's implantation. So I didn't open this door either. I didn't talk about international or anything. It's outside the scope. It's been previously sustained and day after implantation. We would have to respond to this with post date evidence because it was ultimately cleared by Canada. So this is a can of worms that makes our lives a lot more complicated and I didn't

mention Canada in our regulatory issues.

THE COURT: What's the basis?

MR. THOMPSON: Your Honor, this is redirected responding to new material that was elicited on cross-examination with regard to the fact that they were, quote, resolving the difficulties that they had as of July of 2008, and that their experience it was actually improving, and this is simply evidence to show that the complaint rate and failure rate was continued to be unacceptable.

THE COURT: Let me see what this will document says.

(Pause.)

THE COURT: Well, this certainly could be used to impeach a witness who said that these reported adverse incident rates were stable or declining. But this is not the witness to do this with. So as you probably -- you don't have a witness to do this with?

MR. THOMPSON: Your Honor, certainly if the witness said it, that's one thing. In fact, Mr. Keenan elicited that. He elicited that oh, the complaint rate, the failure rate, the complication rate of the Pinnacle was declining and that they had, quote, solved the

problem with it.

MR. KEENAN: That was for the with regard to the Capio, that was the Capio problem. That was the Capio problem. She spoke about extensively. That's a totally different issue than this.

THE COURT: Are you going to have any Boston Scientific representative testify?

MR. KEENAN: We haven't decided yet. John Sherry has been on our will call list. We haven't decided that yet. We want to try to get the case submitted by Thursday at five, and we're going to cut our case back so we can make that happen. This exam has gone much longer I expected, and if this is used it's going to go a lot longer. Those Canada --

THE COURT: Is this a higher rate reported in Canada or in the United States?

MR. KEENAN: United States. But again, Your Honor, this is -- I mean, Canada has entirely different regulatory rules about whether or not devices should be cleared.

THE COURT: Well, this is evidence that there's a higher rate of reported adverse events compared to the predicate Polyform mesh, and there was, unless I'm

misremembering, I believe there was testimony talking about the reported adverse events with regard to this product.

MR. KEENAN: The field assessment. He spent 30, 40 minutes on the field assessment that showed high rates of performance that is in the case. We're not denying that.

THE COURT: What about the fact that there are higher reported adverse events compared to the predicate Polyform mesh.

MR. KEENAN: That's in the case the. Polyform we said had zero and the combination has, what, 175. So that's already in the case. This doesn't add anything beyond that.

THE COURT: Has this witness already testified to do this. Who testified to that?

MR. THOMPSON, judge we just went over the Polyform was low and the Pinnacle was kit was high. That's not a reason to keep it out. That's a reason to support the credibility of the document.

MR. KEENAN: He's bolstering the witness, his own witness. If he wants to use it with our regulatory witness, we can do that tomorrow.

THE COURT: I will, in all probability, let you use it with Boston Scientific's witness, but not with this one.

MR. THOMPSON: All right. Thank you, Your Honor.

(Sidebar conference concluded.)

(Pause.)

BY MR. THOMPSON:

Q. Dr. Parisian, let me do one more thing real quickly. Do you recall that in the amended abbreviated 510k that Boston Scientific provided to the FDA and we can either pull this out and go over it in laborious terms, or we can just remember that Boston Scientific took the position that the Capio device and its method of insertion presented no new or novel techniques --

A. Right.

Q. -- that required further exploitation; do you remember that?

A. Right.

Q. I think that Mr. Keenan has taken back his Prolift, is that going to be in evidence or is that --

MR. KEENAN: If you want it, I'll get it.

MR. THOMPSON: Yes.

MR. KEENAN: It's not my Prolift.

(Pause.)

MR. THOMPSON: Thank you.

BY MR. THOMPSON:

Q. And he talked about the trocars or the entry devices; do you remember that?

A. Yes, sir.

Q. These were these, and he pointed to those six or seven different entry points, do you remember that?

A. Yes, sir.

Q. And then he contrasted it with this Harry Potter looking device, the Capio, and he said that you see, this presents no new or novel differences or changes from these trocars?

A. Right.

Q. Now, Dr. Parisian, in your role as a highly educated and experienced regulatory expert with a fine eye, does this look different than this?

A. Yes.

Q. Does this present a different entry angle than this?

A. Yes.

Q. The representation was made that this was going

to cause less disruption than this with no supporting data?

A. Yeah.

Q. Would that be something that should be relied upon by a medical device company?

A. You mean the company should have gotten data 'cause you're basically putting like a crochet hook in, just poking it around in one incision. If you're going to say it's safer, you need to get data, particularly if you're going to say it in your marketing, which subsequently they did. You need data to support that claim.

Q. I hate to say it, but does it look safer than this?

A. No.

Q. Is it safer because I said it is?

A. No.

Q. How do you know it is safer?

A. I don't know.

Q. How could you tell if it was safer?

A. You can have it used. You can begin by doing the studies looking at cadavers comparing types of injury routes you have by putting that hard ridged thing

into a incision. You can do study with cadavers where you start. You can also do clinical studies, FDA suggested to look at women in a fashion where they have an informed content, and then you follow-up on them. So there are ways to look at that.

Q. The FDA recommended clinical studies; is that right?

A. Yes.

MR. KEENAN: Objection.

THE WITNESS: Well, they didn't recommend.

THE COURT: All right.

MR. THOMPSON: I'll withdraw the question.

BY MR. THOMPSON:

Q. Did the FDA suggest that clinical studies was one way they could address the unknown?

A. Yes, it is.

Q. Did Boston Scientific take them up on their suggestion?

A. No.

Q. Instead, did Boston Scientific make a position to the FDA that this was not new, or novel, and in fact presented the same known risk?

A. Yes. As the expert in the product and the

design, they said to the FDA that there was less risk.

Q. One last couple of questions. This, can we agree, that this is the first time that we've ever used a Capio to insert a Pinnacle pelvic device blindly into the pelvis of a woman?

A. Yes.

Q. And is this the only device that uses the sacrospinous ligament to make an attachment in an Apical device?

A. An anterior device. Yes, sir.

Q. I'm sorry, an anterior device.

Would you pick up the Pinnacle device and go to 00600. Can you do that for me Mike.

Pick up the second paragraph, please?

A. Do you want me to read it.

Q. Let me read it I can go faster. Through the use of the Capio device, the physician avoids blind passages through the pelvic floor anatomy, risk of organ and vessel perforation, as well as hematoma and post-operative bleeding increases with each additional blind passage through the skin and anatomy. The risks due to blind passages are eliminated with the Pinnacle system because of the absence of such blind trocar

passages.

Additionally, no skin incision is required to deliver the Pinnacle device, only the vaginal incision. The absence of the skin incision has the potential to reduce the risk of infection and sepsis to the patient. See that?

A. Yes, sir.

Q. Is there any clinical data to support that assertion?

A. No.

Q. Is it a correct statement to say that the physician avoids blind passages through the pelvic floor anatomy?

A. No. 'Cause you're using a ridged device and sticking it into the pelvis.

Q. The physician doesn't use an endoscope as the prior approval, not approval, the prior clearance of the Capio called for, does it?

A. That's correct. So there's no visualization.

Q. So even in this letter, July 18th -- I'm sorry, this is the amended abbreviated 510k even in that, do you find fault with the description of the process?

A. Yes. And the potential risk for patients.

Q. And do you believe, or is it your opinion to a reasonable scientific certainty that Boston Scientific was on notice of a responsibility to do further inquiry to assure the safety and non-defectiveness of Pinnacle product?

A. Yes, they were.

MR. THOMPSON: Your Honor, that's all the questions I've got. Thank you.

MR. KEENAN: No more questions.

THE COURT: You may step down. Thank you. You're excused.

THE WITNESS: Thank you, Your Honor.

THE COURT: And who is your next witness?

(Pause.)

MR. THOMPSON: Your Honor, I'd like to call Thomas Barba, please.

THOMAS BARBA,

having been first called by the State was sworn on oath, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. THOMPSON:

Q. Mr. Barba, how do you do this afternoon?

A. Tired.

Q. All right. Mr. Barba, I will notice that Ms. Barba has stepped out of the courtroom; is that right?

A. Yes.

Q. Now, Mr. Barba, did we talk about this and decide while you were testifying she would not be present and while she's testifying you're going to wait outside?

A. Yes, sir.

Q. And the reason for that is why?

A. It's too emotional.

Q. How old are you?

A. I'm 52.

Q. And you are a resident of where?

A. Newark, Delaware.

Q. How far away from the courthouse is that?

A. Probably 15 miles, maybe.

Q. What is your line of work?

A. I'm assist manager of a roofing and siding distributorship.

Q. Does that keep you outside or are you an inside guy?

A. I'm inside. I can go in or out as I please.

Q. As the assistant manager, do you visit job sites, as well as work in the --

A. No, sir.

Q. Tell me where you work?

A. I work in Newark in Ogletown, Newark Delaware.

Q. How do you spend your days?

A. I sit at a desk most of the day.

Q. Okay. Mr. Barba, how many times have you been married in your life?

A. Once.

Q. And who are you married to?

A. My beautiful wife Deborah.

Q. How long have you and Ms. Barba been married?

A. It will be 27 years this November.

Q. Has she worked outside the home during your marriage?

A. Yes. Yes, sir.

Q. And what is her profession, what is her job?

A. She's been in the banking industry most of her life.

Q. When you say banks industry, is she a bank teller?

A. She worked for JP Morgan Chase, Bank of New

York, they all got a acquired Bank of New York, they got acquired by chase and then they got banks kept getting acquired. She got laid off from there after 17 years and she went into a banking tellership after that.

Q. I see, and how long was she in the banking tellership?

A. She worked for Citizens I believe for 7 years before she got laid off, and then she started with M and T Bank. I think she was there not quite a year, maybe a little over a year until she lost her job.

Q. And that was just recently?

A. In December.

Q. All right. In her job, does she -- sounds like it's a -- there's some responsibility. Does she have to be bonded?

A. I don't believe so, no, sir.

Q. Does she -- is she accountable for handling sums of money and accounting for it accurately?

A. Yes, sir.

Q. How does she take her job? Is it a lark, or is it just something to put groceries on the table, or how is she about her career?

A. She takes her career seriously as she does

everything.

Q. What do you enjoy, and actually let me split this into three distinct time periods, if that's okay. I'm going to pick days that you sat here for a week now so you'll understand the dates I pick. The first one I'm going to pick is a time before about 2007/2008 I want to talk about that time period, if I can. Okay?

A. I'll try to remember.

Q. Around 2007, 2008 what did you do and Ms. Barba enjoy, what kind of activities?

A. We used to go to Chincoteague. We used to go down to the beach once in a while. We used to go to parks all the time walking. I like the beach, she likes the mountains. So we try do a little bit for each of us.

Q. Who does the, before 2007, who did the cooking in the house and that sort of --

A. My wife did.

Q. Keeping the place clean?

A. My wife did. I did the outside, and she did the inside.

Q. And you fulfill your job of messing it up, I assume?

A. I try not to. I don't want to get in trouble.
Q. All right.
A. Happy wife, happy life.
Q. Mr. Barba, would you describe your married life idyllic or a fantasy land of joy?
A. No, far from it.
Q. Tell me your relationship with Ms. Barba for your married life?
A. Today?
Q. No. Before 2007?
A. Like any couple, we, you know, we have our problems. We might not talk for a couple days, but then it comes back. That's how we try and stay married, we took vows that we'll try to stay together forever. That's what we -- so we have our arguments.
Q. Do you view your marriage as a life-long bond?
A. That's what my vow was 26 years ago.
Q. Let me direct your attention now to around 2008 into 2009. Did there come a time when Ms. Barba needed to be seen for a stress incontinence?
A. She had to go to the doctor because after we had intercourse, she was having problems, and she didn't know what -- she noticed a bulge down there she would

complain about. So she made an appointment with Dr. Carlson, I believe it was. I don't know if she went to her family doctor first, or if she went straight to Dr. Carlson.

Q. Let me ask you this straight up because we sort of approach this subject, looking at 2007/2008, did you and Ms. Barba enjoy a strong and active intimate life together as husband and wife?

A. Yeah. 'Cause we have to -- we plan date nights because we didn't want our, you know, most marriages split up as they go on. So to keep -- we did our Wednesdays and Saturday nights. We tried to do that every week. And it was well. Unless we were fighting then, of course, naturally I try to make up before, if it didn't happen I'm not saying we did it every Wednesday and Saturday because there were times we were not getting along.

Q. But you did your best to make up before Wednesday and Saturday?

A. I tried. She's a smart woman. She knew what I was doing.

Q. She questioned your motives, I'm sure. She's gone to see Dr. Carlson. Do you recall her having the

operation and you have sitting here for a week so we can actually just say the Advantage Fit SUI device and Pinnacle pelvic floor device. Do you remember her having that operation?

A. Yes, sir.

Q. Now, did you sit in on the discussions with Dr. Carlson?

A. Not the original visit, but when they started discussing what he wanted to do to my wife, I took off work to go with her to go over the procedure.

Q. And did you go and did you sit with him?

A. Yes, sir.

Q. In your discussions or in talking with Dr. Carlson, did he describe to you that this procedure was going to be permanent?

A. I don't recall it being permanent. I don't recall that, no.

Q. Did he describe for you what, if anything, he could do if the operation, or if the procedures failed and had to be undone?

A. We never went over that. I don't recall him talking about having -- whatever having to come out. I recalled him saying it was going to fix her problem and

that he had very good success rates with it. That's the extent of it. I really don't believe he ever discussed about failure.

Q. Now, we've seen, and you've actually sat here and seen it that Dr. Carlson had Ms. Barba sign several consents to surgery. Did you sign anything?

A. No, sir.

Q. That was she signed those?

A. Yeah. We believed it was for the surgical procedure, like all operations you have to sign paperwork to have surgeries.

Q. After that operation, do you remember her recovery period?

A. Yeah.

Q. And what was it like?

A. Well, she had to have a catheter in her for a week. I knew when Dr. Carlson told her after surgery she wasn't going to be happy because that's a fear of hers. And that was not good, but then we came out and she started to progressively get better.

Q. Do you know whether or not she had recurrent urinary tract infections over that summer?

A. I believe she did. It was so long ago, so I

don't -- I know she had some problems, I don't know the extent of her UTIs.

Q. Do you recall whether or not she was suffering from any pain during that period of time, post operation and into the summer and into the Fall?

A. Just from the surgery. There's always pain after that, especially what she went through.

Q. Was she put under some sorts of restrictions in terms of her level of activity in the things she was supposed to do?

A. Yes, she got spoiled by me. I had to do everything.

Q. Who was doing the cooking and the cleaning around the house?

A. I was, or we were going out more to eat. And I cleaned the best I could. It was never good enough.

Q. Were you -- would you describe Ms. Barba as a compliant patient?

A. Yes.

Q. Did she do her best to follow the doctor's instructions?

A. Oh, yes. In everything she does she follows the letter of the law.

Q. When you were -- I'm going to direct your attention to June 16th. Were you at home when Ms. Barba had the workman over to the house?

A. No, sir.

Q. And that was the day that the vicious dog attacked and bit the workman and she violently had to pick him up and it was terrible. Do you remember that incident?

A. Yeah, but my dog never bit nobody.

Q. Do you recall what your dog's name?

A. Mickey, my boy.

(Pause.)

BY MR. THOMPSON:

Q. All right. Make that bigger.

Mr. Barba, is this the dog we've been talking about for the last week?

A. Yes, it's a little hyper.

Q. This is Mickey?

A. That's my boy.

Q. You did not see the events of June 16th you were at work?

A. Yes, sir.

Q. When you got home, did you know that your wife

had gone to see the doctor?

A. Yes, she had called and told me she was going to go to be on the safe side.

Q. When you got home and you had your evening routine, and into the next day and into the next week, did Ms. Barba suffer any adverse effects, or any problems from the events of the day of June 16, 2009?

A. No. We didn't even remember June 16th of 2009, because it was never an issue.

Q. All right. And from that day forward she -- this was not an incident, and this was nothing that you guys worried about?

A. No.

Q. Now, she was having trouble regaining the use of her bladder, though wasn't she?

A. As I recall, she wasn't voiding all the way properly.

Q. This is not something that she shared with you, I bet?

A. My wife doesn't complain to me at all.

Q. Were you aware that she was having to squat to get a flow, or to finish voiding?

A. I don't recall back in 2009. She might have

said something to me.

Q. Do you recall that over the period of time from July, August, September into the following year, do you recall her having urinary tract infections and having trouble with her urine?

A. Yeah, because the UTIs got involved in our date nights.

Q. Just explain what that means?

A. They're painful, they're not -- so if you had an infection down there, she wasn't in the mood.

Q. So that meant that the date nights were suspended?

A. It didn't happen that day.

Q. Can I safely say you entered into a new phase with your wife?

A. Since the first surgery of 2009, my life has changed with my wife.

Q. Tell me how your lifer has changed?

A. She's not the same woman, especially now. She has no energy. She has no drive. She don't want to do nothing. She's -- she's fed up.

Q. And is she anxious?

A. She very, very upset and don't know what the

04:18:02 future is going to hold. She knows she's going to have
04:18:06 another surgery, she's afraid, and because she doesn't
04:18:10 know what the outcome is going to be.
04:18:12 Q. Do you recall her seeing Dr. Vakili?
04:18:18 A. Yes.
04:18:19 Q. And do you recall him performing surgery on
04:18:21 her?
04:18:21 A. She went to Dr. Vakili on her own the first
04:18:21 time I don't know how many visits she went before I
04:18:24 went, when it got to the point we were discussing the
04:18:26 surgical procedure, I took off work to go with her so I
04:18:31 can be there for her if she wants me to understand
04:18:34 what's going to happen to her.
04:18:36 Q. Did Dr. Vakili perform a revision where he took
04:18:40 out the Pinnacle?
04:18:41 A. The mesh?
04:18:42 Q. Yes.
04:18:43 A. Wadded up mesh, yes.
04:18:44 Q. Do you know whether or not any was left in her?
04:18:48 A. We were told he got the entire -- we're finding
04:18:52 out here that she has stuff left in her.
04:18:54 Q. I see. Following that surgery, did she have
04:18:58 trouble with going to the bathroom with pain -- how was

she?

A. There again, she woke up and Dr. Vakili told me she was going to have to go home with the catheter and there again, not happy. So we knew and, of course, when she woke up and found out she was very not happy. But then it never came out. She was stuck with it for, I don't know how long it was, 7 months maybe.

Q. Are you aware that she kept a diary or a record of her catheterization?

A. Yes.

Q. Was she trying to do exactly what the doctor told her to do?

A. Yes.

Q. You again, this is very private, were you aware that she was self-catheterizing?

A. Yes, sir.

Q. Did she ever -- did she do it out of your presence?

A. She never done it in front of me.

Q. She was continuing to go to work, though, wasn't she?

A. Yes, she had to or she would have lost her job.

Q. And if she's self-catheterizing a number of

times a day was she catheterizing at work, as well?

A. Yeah, she would come home stressed out because she was taking longer in the bathroom than she was supposed to. She would get talked to by her manager.

Q. Did there come a time when you went to see or she went to see Dr. Wright?

A. Yes, sir.

Q. Did you go along with her, you met Dr. Wright?

A. I had to take off to take her down there. She doesn't like to drive 95 and, of course, Baltimore is not around the corner. I had to take her down there.

Q. Do you recall that trip down there?

A. Yes.

Q. After that surgery, was she in pain from the surgery?

A. Yeah. Like all surgeries she'll have her pain.

Q. Did she have a recovery period after that surgery?

A. Yes, sir.

Q. And was she limited in her activities for a period of time?

A. Not as much as the first two, 'cause it wasn't as intrusive. From what I understand they just went in

there and cut the sling.

Q. Mr. Barba, I want to now go to the third period of time in your testimony. And that is the period of time following Dr. Wright and following her immediate recovery and up to the present and into the future. Mr. Barba, how would you describe Ms. Barba presently?

A. She's not the same woman I married. And she's -- she tells us that we're roommates now. She's not husband and wife. She says.

(Pause.)

BY MR. THOMPSON:

Q. And what is your vision, or what is your thoughts about the future?

A. Don't know.

Q. Mr. Barba, do you still love your wife?

A. Very much.

Q. And, Mr. Barba, when you see her in this condition, how do you feel and what is your response?

A. It breaks my heart. I hate to see her go through it.

MR. THOMPSON: Your Honor, I have no more questions. I would like to make the photograph and exhibit please, Plaintiff's 35 if that's okay.

Mr. Barba answer any questions Ms. Shields has.

(Pause.)

MR. THOMPSON: Your Honor, could we approach just for a second.

THE COURT: Yes.

(The following sidebar conference was held.)

MR. THOMPSON: Your Honor, I doubt Ms. Shields is going to go there, but if you remember after opening statements well talked about this incident back in 2002 or so about the dog bite. And I would like to object and ask that that not be a matter of cross-examination.

MS. SHIELDS: I won't ask about that.

THE COURT: All right.

MR. THOMPSON: Thank you.

(Pause.)

(Sidebar conference concluded.)

BY MS. SHIELDS:

Q. Good afternoon, Mr. Barba.

A. Good afternoon.

Q. When you're testifying and you're testifying about date night, I know it's a difficult subject for you, but you're talking about the inability or strain on the ability to have sexual intercourse with your wife;

is that right?

A. Current? There is no sexual intercourse with my wife currently.

Q. But when you talked about date night, are you referring just solely to the ability to engage in the acts of sexual intercourse?

A. Yes, ma'am.

Q. Because there's nothing else that is preventing you from being able, you having a date night with your wife?

A. We do that every other night.

Q. Okay. Back before Ms. Barba went to see Dr. Carlson to get some evaluation of the problems that she was having, your ability to engage in sexual activity with your wife was being affected by the prolapse condition, and by the vaginal atrophy that she had at that time, isn't it right?

A. With the prolapse, that's what was causing her to bulge that bulge being down there is what was bothering her.

Q. And bothering her, it was causing pain during intercourse; right?

A. It was a discomfort, not a pain she was -- we

were able to have sexual intercourse.

Q. And she was not just talking about pain during intercourse, but she was telling you that she was having pain the next day after an evening where you two had date night; correct?

A. Not prior to May 2009, she didn't have pain. She had discomfortable with sex. Prior, before the surgery, she did not have pain during sex, she had discomfort during sex. If it was painful, she wouldn't be able to enjoy sex.

Q. I mean -- let me do this, Your Honor may I approach the witness with a copy of his deposition?

THE COURT: Yes.

BY MS. SHIELDS:

Q. Mr. Barba back on November 21st, 2012, you and I sat down in a room and I asked you some questions under oath?

A. Correct.

Q. And I'm going to ask you to --

MR. THOMPSON: Your Honor, I believe Mr. Barba wants a pair of reading glasses.

THE WITNESS: Yes. I think they are in my wife's pocketbook. I'm sorry.

THE COURT: That's all right.

(Pause.)

MS. SHIELDS: Your Honor, may I.

THE COURT: Certainly.

THE WITNESS: Thank you.

BY MS. SHIELDS:

Q. Mr. Barba, I'm going to ask you to take a look on the bottom of page nine and I asked you the question how frequently would she have the pain complaint, was it every time you had intercourse? And your response was the next day?

A. Yeah, that was my response.

Q. And to be fair to you if we go to the next page you did talk about discomfort, but the question I have really is whether we characterize it as pain, hurting, or discomfort. If problems she was experiencing during intercourse weren't just during the actual act of intercourse but they continued into the following day; right?

A. Yeah I'm assuming it was because of the prolapsed bladder you know sex is the bulge is there so I can say it's like being punched in the arm a couple times.

Q. So this discomfort and bleeding, right, she also had some bleeding?

A. I only recall that once. She's never -- I only recall her bleeding once.

Q. Okay. But in that time frame, it was to the point where it was beginning to have an impact on your ability to engage in relations with your wife and that was one of the reasons why she went to see Dr. Carlson to get some attention; right?

A. We still had our date nights and if it was that painful, we wouldn't have had our date nights. It was discomforting to her, but she we still had our date nights yes, it was more uncomfortable that's why she found out something was wrong. That's why she went to a doctor to find out if it could be fixed.

Q. And your wife asked you to come with her to the second visit with Dr. Carlson where surgical options would be discussed?

A. Every doctor she's ever had surgical options I'm at.

Q. And you were there, and you had an opportunity to ask Dr. Carlson some questions about the surgical procedure that your wife was going to undergo; isn't

that right?

A. I had the opportunity, yes, ma'am.

Q. And the only question that you asked Dr. Carlson was about sexual intercourse, and whether having the surgery was going to make it normal again, whether it was going to fix her; isn't that right?

A. I hate to be selfish, but that's true.

Q. Now, after the surgery, the hope was that things were going to get better, and your wife was going to be able to resume sexual intercourse without discomfort, and that her bladder function would be normal, but that didn't happen, did it?

A. Yeah, but she got better. She got better. We were able to have sex for a time being there. Then it started getting worse. So yeah, she was able -- we were able to resume our sexual activity.

Q. During what period were you able to resume sexual activity?

A. I don't know exact dates. I know she had a recovery time. I think six to eight weeks. So we did nothing for six to eight weeks. I'm assuming when she felt better and got the clearance, we would start and we went on our old merry way, we had a fight, date nights

didn't happen, life happens, and then towards another time when she decided to go to Dr. Vakili, she was gutting UTIs, it was getting more difficult with intercourse that's why she decided to go to Dr. Vakili.

Q. You were here the other day when Dr. Carlson testified; right?

A. Yes.

Q. And we walked Dr. Carlson through his record. And, in fact, according to Dr. Carlson's record, your wife never regained normal voiding function following the surgery with Dr. Carlson; isn't that right?

A. She had to stand up to finish, but that didn't effect the ability of her having sex.

Q. Okay. You said that UTI effected the ability for having sex, and by the time she got to Dr. Vakili she had told Dr. Vakili she had been having problems with voiding, being able to void her bladder entirely, all the way back to the time of Dr. Carlson, and that she was having six to eight UTIs a year; is that right?

A. Yes. I don't know how many there were per year, but when she he will a UTI, we didn't have sex. When she didn't have a UTI we did have sex.

Q. What you're telling us there was a period of

time after the surgery with Dr. Carlson when you were able to engage with sexual activity with your wife, she had no pain and discomfort?

A. I'm not a saying there was no discomfort. The pain was nothing like it was after the second surgery. If she started getting discomfort up to the -- where she decided to go to Dr. Vakili, pain was getting -- the pain was getting worse between the first surgery. She got better, time went on, she was getting UTIs, no sex, very painful. When there was no UTIs and no fighting, we tried to get in our date nights. Close to when it was October 2009 or '10, 3 months before that she couldn't get an appointment for 3 months, that takes you back to, what, July or August. So July, June, July, August of that year, I think she started having problems feeling more pain with sex and getting UTIs. That's why she had called Dr. Vakili. I think she went to Dr. Ting, her family doctor complaining first. She's the one that recommended Dr. Vakili.

Q. Right. So for months after Dr. Carlson performed surgery, your wife had UTIs repeatedly and she had to stand to urinate. And Dr. Carlson kept telling her it was normal, it was the healing process, right, do

you remember that?

A. I remember him saying that.

Q. And you didn't think that was right; right?

A. She didn't have to stand she had to squat, standing pee, standing to pee, woman don't stand to pee.

Q. They are not supposed to, right?

A. Right my wife didn't stand to pee, she had to squat to finish peeing.

Q. You actually told your wife she should get a second opinion because you were dissatisfied with the fact that she wasn't getting to regain normal bladder function after Dr. Carlson's surgery; right?

A. I believe Dr. Ting told her that and she discussed it with me. Yes, we were frustrated. She opted to go to see Dr. Vakili on the reference of Dr. Ting.

Q. Okay. And now, if your wife testified that sexual activity got less painful after Vakili and even less painful after Wright, would you disagree with that?

A. Well, my wife was catheterizing herself for 7 months. So there wasn't too much sex involved between Dr. Vakili and Dr. Wright. Things changed dramatically after the second surgery.

Q. Let me ask you -- well, let me ask you this: When you got to Dr. Wright, and you said your wife is doing better now than she was doing before she had the surgery with Dr. Wright; isn't that right? You'd agree with that?

A. She's not doing better. In the sense she can urinate on her own, yes, she's doing great. But that's the better sense from not being able to urinate to being able to urinate, that's better.

Q. In some respects she's doing better?

A. She can urinate on her own, she does not have to self-catheterize. I would consider that better.

Q. What did Dr. Wright tell you about what was causing your wife's problems when she got to see him?

A. The first visit?

Q. At any time did he explain to you what he thought was the problem?

A. He thought the sling was put in or was under tension.

Q. He thought it was under tension meaning too tight from the beginning?

A. I don't know if he said from the beginning. I might have put that in my words, but it was under

tension.

Q. And you're saying you might have put that in your words, that's actually what you said at your deposition?

A. Yeah. But I'm going off from a memory two years ago or maybe three years ago.

Q. Your dog Mickey looks like a cute dog and he may be a very friendly dog. He weighs more than 10 pounds correct?

A. Correct.

MS. SHIELDS: Thank you, Mr. Barba.

MR. THOMPSON: Your Honor, no redirect, please.

THE COURT: Is that it for today? Is there anything we can --

MR. THOMPSON: Your Honor, I don't believe we can finish anybody today.

THE COURT: I think this is good place to stop for the time being. We will reconvene tomorrow morning at 10 o'clock. Have a safe trip home.

(The jury left the courtroom at 4:34 p.m.)

THE COURT: Is there anything we need to discuss at this point.

MR. KEENAN: Not on the record.

04:38:27 THE COURT: All right. We'll go off the
04:38:29 record.
(Whereupon the proceedings were adjourned.)

CERTIFICATE OF COURT REPORTER

I, John P. Donnelly, RPR, Chief Court Reporter of the Superior Court, State of Delaware, do hereby certify that the foregoing is an accurate transcript of the proceedings had, as reported by me, in the Superior Court of the State of Delaware, in and for New Castle County, in the case herein stated, as the same remains of record in the Office of the Prothonotary at Wilmington, Delaware. This certification shall be considered null and void if this transcript is disassembled in any manner by any party without authorization of the signatory below.

WITNESS my hand this 18th day of MAY, 2015.

Cert. # 161-PS

/s/ John P. Donnelly, RPR
Chief Court Reporter